Annual Report 2014

ENGLISH

Chiesi

Index

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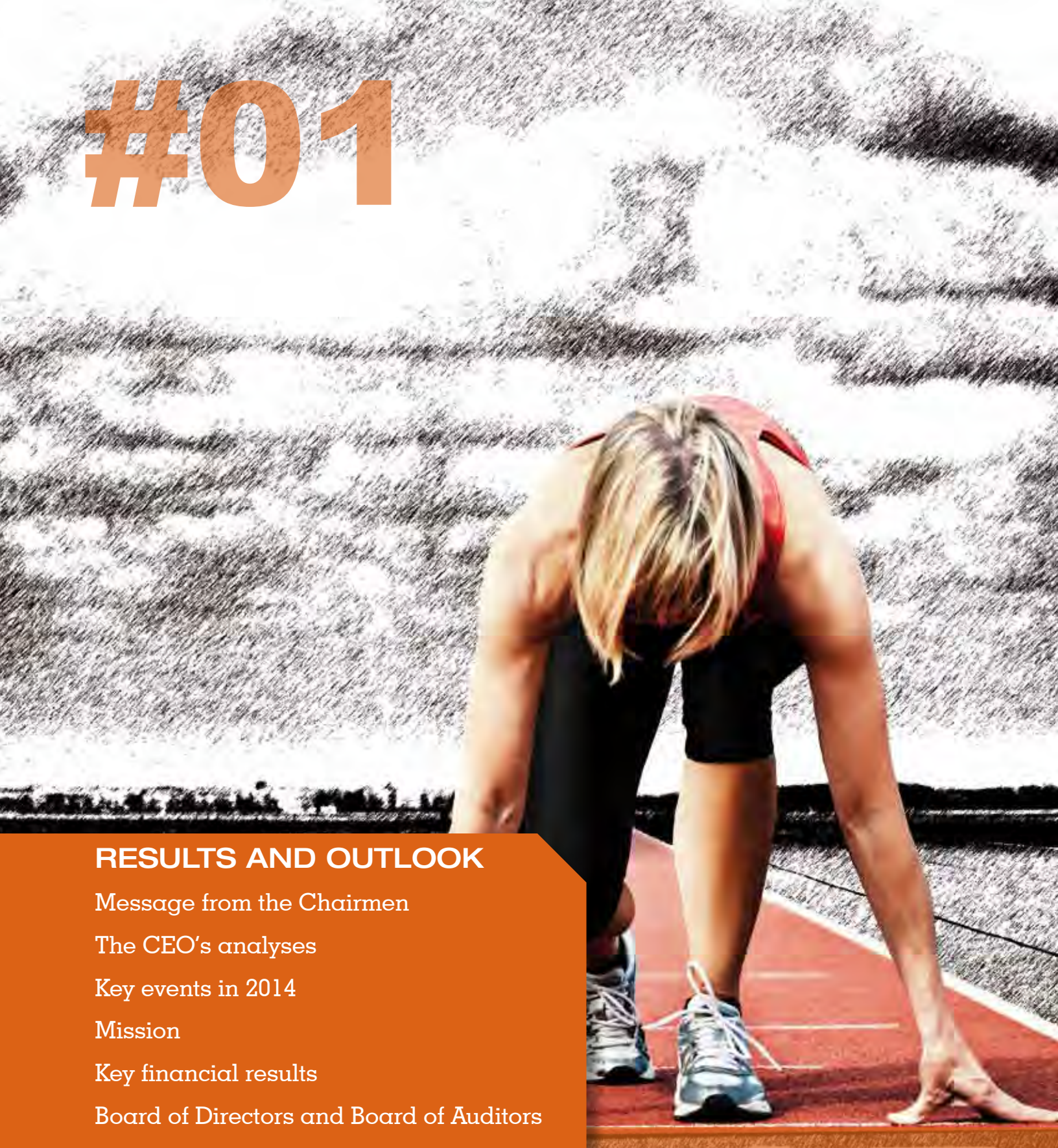


RESULTS AND OUTLOOK

2015

The Chairmen's message

Alberto Chiesi
Chairman

Paolo Chiesi
Vice Chairman and R&D Director

Initiatives aimed at strengthening the Chiesi Group continued in 2014, both regarding its capacity for sustainable growth and the optimisation of Research & Development and internationalisation activities.
Sales continued to perform well, and achieved an organic growth of 8.4% on the previous year to reach 1.342 million Euro, and with an even better economic result.
It was a dynamic period for all of the affiliates, and in several cases growth went into double figures, excepting for a few countries affected by the difficult economic situation at local level.
International sales consequently stood at 77% of the total, with significant growth in the USA, the Emerging Countries and Northern Europe.
The results achieved are particularly commendable when compared to the world pharmaceutical market trend, which according to IMS grew by 5.8% in Euro for retail sales in 2014.

In 2014 Chiesi became one of the 46 largest innovative pharmaceutical companies at global level, with a growth rate placing it among the most advanced in the sector.
Additional investment continued to be made in Research & Development, reaching 236 million Euro and distributed among over 40 projects at various stages of development.
Furthermore, investment to reinforce the industrial plants and acquire new projects and research equipment has been in excess of 87 million Euro, to which 89 million were added for the acquisition of the total capital of Chiesi USA.
Our future growth remains linked to three parameters that we regard as indispensable:

- innovation
- focus on selected therapeutic areas
- global geographical presence.

The results achieved over the years are confirmation of the validity of the growth generated so far. The products either wholly or partially developed by Chiesi R&D generated 73% of global sales in 2014: at the same time this is also recognition of the Group's capacity to innovate and the solid foundation on which it will build future growth.

The respiratory market will continue to be our central focus, not only because of the significant contribution to sales (over 58%) but also the high levels of investment in the research and development of new products and those already available. For the latter, the development process is oriented both towards

further improving the way they are administered (e.g. Foster NEXThaler, Curosurf nebuliser), and in demonstrating their clinical efficacy for new indications, such as in the case of the recent Foster indication for COPD.
The Foster NEXThaler launches (Austria, Slovakia, Slovenia, Hungary, the UK, France, Belgium, and Brazil) and the Foster roll-out for COPD represented a significant commitment for the company, yet also confirmed its increasingly recognised international leadership, creating the foundations on which to develop the turnover in the next few years. The market shares of the two products have increased dramatically in all the countries in which they are present.
The launch of Envarsus in Germany, which will shortly be followed by those in Europe, Russia and Turkey, opens the doors for the company to the transplant therapeutic area. This immunosuppressant, indicated for the prevention and treatment of organ rejection in adult patients undergoing kidney and liver transplants, provides greater bioavailability and an optimal pharmacokinetic profile compared to its major competitors, thus helping to improve patient management and quality of life. Envarsus will make an invaluable contribution to building on the Group's turnover in special care.
The European registration of Holoclar, the first Western drug based on autologous stem cells indicated for corneal regeneration in patients with severe corneal chemical or thermal burns, represents a remarkable and undisputed success. Holoclar will be marketed by Chiesi and is produced by Holostem, a spin-off which the Group created as a joint partnership with the University of Modena and Reggio and to which it has given and continues to give a significant contribution both from an economic and Research & Development point of view.
Glybera, the first drug for gene therapy registered in the Western world and indicated for the treatment of lipoprotein lipase deficiency (LPLD), has completed the price determination process in Germany. This product, aside from providing a therapy for a rare and debilitating disease, opens up new prospects for the future treatment of other genetic diseases.
Lamazym, indicated for the treatment of alpha-mannosidosis, continues its development with a phase III pivotal trial.
These products are confirmation of the company's ability to provide effective solutions for the treatment of diseases which as yet have no cure through new therapeutic paradigms.
Within the scope of the internationalisation process, the acquisition of Cornerstone is now complete, resulting in the creation of Chiesi USA Inc. The US affiliate, whose main focus is commercialising hospital products and specialist drugs, represents an important element in the international development strategy due to its presence in the world's largest pharmaceutical market and wide range of therapies.
The Chinese affiliate is operating in a rapidly evolving market; the availability of products such as Foster, Clenil, Curosurf and Peyona means that its contribution to Group sales is becoming increasingly important and is destined to develop further in the future.
The growth that the company is achieving requires both the Research and Development infrastructure and that of production to be continually updated and improved. 2014 was characterised by the creation of new industrial structures, and in particular the new departments built for the production of Curosurf due to the growing global success of the product: the Modena plant produces the active ingredient and the finished product is then made and packaged in Parma. The new department for the production of powder inhalers used for Foster NEXThaler is housed at the French plant in Blois.

The Group's organisational and governance model continues to evolve, both to optimise the evolution of its product portfolio and interpret the changes to international markets and their regulatory systems. The recent expiry of the marketing agreement for Provisacor in Italy has called for a reorganisation of the marketing functions and salesforce networks, albeit without requiring a reduction in the workforce. On the contrary, the total workforce increased from 3,885 people in 2013 to 4,077 at the end of 2014.

Among the acknowledgements received by the Group last year, the Top Employer Award is of particular note. Awarded for the sixth year running in Italy and third in Europe, it is based on objective assessment criteria including remuneration policies, working conditions, training, career opportunities and company culture.

At the same time, our commitment to social responsibility continues with precise aims: safeguarding the environment, improving safety at work, providing funding for a number of research programmes and medical training initiatives and actively contributing to projects of proven social utility. In addition, the Chiesi Foundation carries out an ever-important role, expanding the number and range of activities in support of research and humanitarian initiatives for the prevention and treatment of various diseases in some of the world's poorest countries.

Once again we would like to express our appreciation to everyone at Chiesi for the quality of their work and the positive results they have achieved in spite of the unfavourable economic situation. It is thanks to their passion for excellence and ability to work as a team that even the most difficult challenges are tackled with determination and efficacy.

The spirit of last year's message still holds true: the sustainable development of the Group is based on a climate characterised by team effort, a desire to improve and full respect for the values – that are fundamentally important to us – of the integrity of personal commitment and of truly valuing every single contribution, providing it is of the highest quality. We are confident that these conditions will remain unchanged and will be supported with sufficient energy, and therefore place our trust in the future.

Alberto Chiesi - Paolo Chiesi

The CEO's analyses

Ugo Di Francesco
CEO or Chief Executive Officer

Growth and investment: these are the key words which best characterise the Chiesi Group's performance in 2014. Sales reached €1.342 million and were up by 8.4% on the previous year, around two points higher than the global market performance.
This result has enabled the Group to move up the global ranking of innovative pharmaceutical companies from 50th to 46th place.
EBITDA reached €372 million, equal to 27.8% of sales, and slightly lower compared to 2013 because of the high levels of investment in research and development, which totalled a record € 236 million, equal to 17.6% of sales.
This remarkable financial commitment to innovation is the necessary premise for the efforts made by the Group to develop new products in all the therapeutic areas it is committed to. At the same time, this lays the foundations for the consolidation of its leadership in traditional therapeutic areas, such as respiratory diseases and neonatology, and to continue establishing itself in the treatment of rare diseases and advanced therapies.
Foster, Curosurf and Clenil, the Group's three most important products by turnover, have achieved extremely positive results: in particular, Foster has recorded a sharp increase in market share in almost all the 47 markets in which it is present directly or through related brands. Foster, NEXThaler and related brands have generated overall sales for more than €411 million, up by around 21% compared to 2013. Curosurf has further consolidated its global leadership in the treatment of respiratory distress syndrome in premature neonates, with sales of €175 million, increasing by 8.1% compared to 2013. Clenil, a successful product for decades in numerous markets, has generated sales for over €171 million and a growth rate of 5.1% compared to the previous year.
All the geographical areas have made a contribution to achieving these results: the North – Central Europe (+12%), the Emerging Countries (+9.2%), the USA (+8.4%) and South Europe (+4.6). The distribution of growth is confirmation of the validity of the Group's long-term internationalisation strategy, thanks to which Foster and the other Corporate products are now highly valued in an ever-increasing number of markets.
In 2014 the percentage of the Group's turnover represented by their sales totalled 73%, a result destined for further growth in the future.
The global presence of the Group is increasingly prominent: this is clearly shown by the growth in sales generated from outside the domestic market, which now stand at 77%.
The capital gains provided by the sales of the Group's proprietary brands lay the foundations for an increasingly effective development policy: in addition to the €236 million in Research & Develop-

ment, the Group has invested €87 million in new industrial equipment and €89 million for the acquisition of the total capital of Cornerstone Therapeutics, followed by the subsequent launch of the new affiliate Chiesi USA. Three key results have therefore been achieved: a significant push for new product development and the triple association in particular, an increase in the production capacity of Foster NEXThaler (Blois plant) and Curosurf (Modena and Parma plants) needed to meet the growing demand, and the presence of a Group affiliate fully operative in the largest pharmaceutical market in the world. Thanks to products such as Cardene RTU, Zyflo and Curosurf, Chiesi USA has established the level of quality of its specialist product range for hospital care, contributing significantly to global sales.

The R&D teams have reached a number of important objectives in 2014: aside from obtaining marketing authorisation for innovative products such as Holoclar and Envarsus, they have submitted two applications for the European marketing of Foster and NEXThaler, which are able to provide severe asthma sufferers with a higher dose of the steroid by inhalation.

A considerable commitment is dedicated to the clinical trials on the triple association, which includes a steroid (beclomethasone) and two different bronchodilators (formoterol and glycopyrronium) in a single inhaler. The new product is being developed with both the inhalers (pMDI and NEXThaler) and is targeted for the treatment of both COPD and asthma. The clinical pivotal trials for the triple association are currently on schedule, and making rapid progress in view of the future submission.

The candidate respiratory drugs in the most advanced phase of development include a new phosphodiesterase inhibitor for inhalation and three new anti-inflammatories, which have now successfully entered full development. The muscarinic antagonist beta agonist (MABA), a double-mechanism of action candidate drug, has made good progress.

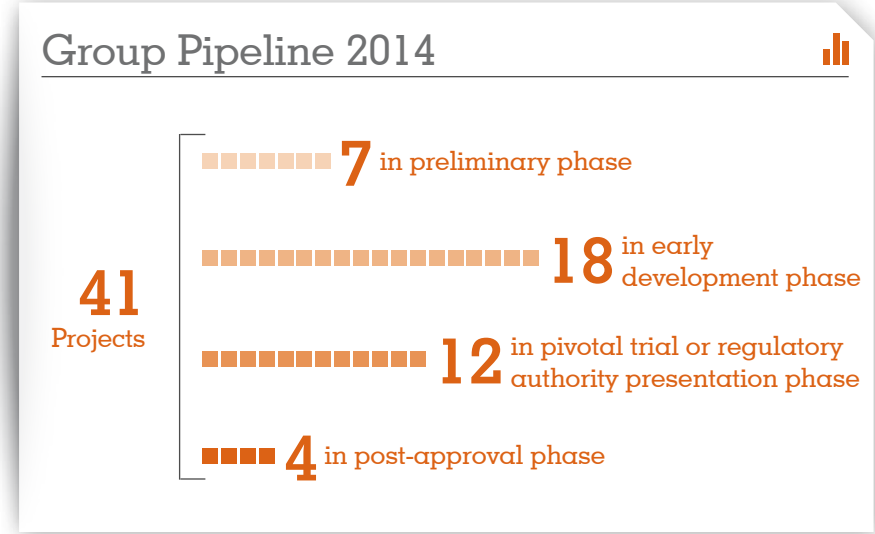
In neonatology, the proprietary minimally-invasive catheter for the administration of Curosurf (LISA) has also moved forward, having already received positive feedback from European regulatory authorities.

With regard to special care, the NEuroSIS trial has also been completed. This is designed to evaluate the preventative effect of budesonide on bronchopulmonary dysplasia (BPD), a common cause of morbidity and mortality in pre-term neonates.

Overall, at year end there were 41 projects in the Group's pipeline: seven in a preliminary phase, eighteen in an early development phase, twelve in pivotal trial or regulatory authority presentation phases and four in post-approval phase. This level of activity, in sharp contrast to the 26 trials active at the end of 2013, is confirmed by the 17 new innovative patents deposited in 2014.

Future growth will therefore be guided by capacity for innovation but also by the selection of new opportunities deriving from the acquisition of companies and products whose characteristics align with

Group Pipeline 2014



the Group's strategy. Of note in this regard is the creation of the Venture Capital fund, Chiesi Ventures, set up jointly with A.M. Pappas & Associates, with the aim of identifying and providing investment for the most interesting emerging opportunities in the special care area. At the same time it will also extend the network of Chiesi contacts in the USA with academic institutions, Venture Capital investors, patient organisations and start-ups dedicated to developing therapies for rare diseases.
The availability of innovative products in gene therapy (Glybera), regenerative medicine (Holoclar) and the prevention of organ rejection (Envarsus) not only enrich the Group's portfolio but also its cultural wealth. In the case of Glybera and Holoclar in particular, it is not out of place to regard these drugs as part of a pioneering approach to entirely new sectors of medicine, which on the one hand provides therapeutic solutions for serious health problems that until recently had no treatment option yet on the other opens up unexplored problems. An example of this are the aspects relating to access to reimbursement for these drugs, whose benefits are expected to last for many years and prevent high levels of expenditure for national health services. The availability of such products creates entirely new perspectives not only for the companies that produce them but also because of the innovative approaches which government spending authorities will be expected to evaluate.
There is consequently a growing need for the Group to develop specific specialist skills in order to deal with the shift generated by this innovation. In this regard, the internationalisation of careers represents an invaluable resource. The ever-growing number of international positions promotes the diffusion of successful experiences and the professional enrichment of those gaining this experience first-hand. The quality of the work benefits from this internal contamination and, combined with the attention constantly dedicated by the whole organisation to its people, ensures that what the Group offers professionally is particularly attractive to the job market. This is confirmed by the Top Employer Europe award, assigned to the company for the third year running. In essence, this means that an increasing number of affiliates are considered leading companies in terms of the quality of the jobs they offer in their countries.
The common denominator uniting the desire for economic growth, the push for innovation, the search for quality and focus on people lies at the heart of passion for excellence. The ownership, the management and all the people in the Group recognise this as the distinctive trait with which they can identify themselves and undertake to reflect this in their daily work. It is thanks to their dedication and ability to work as a team that even the future's toughest challenges will be tackled with determination and confidence.

Ugo Di Francesco

Key events in 2014

- The EMA registers Holoclar, the first regenerative therapy approved in the Western world, for autologous stem-cell corneal reconstruction
- Envarsus, indicated for the prevention of rejection in the transplant of kidney and liver in adult patients, receives marketing authorisation from European regulatory authorities
- The Chiesi Group completes the acquisition of Cornerstone Therapeutics, renamed Chiesi USA
- Building of new Curosurf production facilities-(Modena and Parma) and NEXThaler (Blois)
- Significant increase in Foster and Foster NEXThaler market share in the 47 countries where they were launched.

Mission

Our aim is to be recognised as a research-focused international Group, able to develop and commercialise innovative pharmaceutical solutions to improve the quality of human life.
We want to maintain a high quality entrepreneurial team characterised by self-confidence and a collaborative spirit.
Our goal is to combine commitment to results with integrity, operating in a socially and environmentally responsible manner.

Key financial results

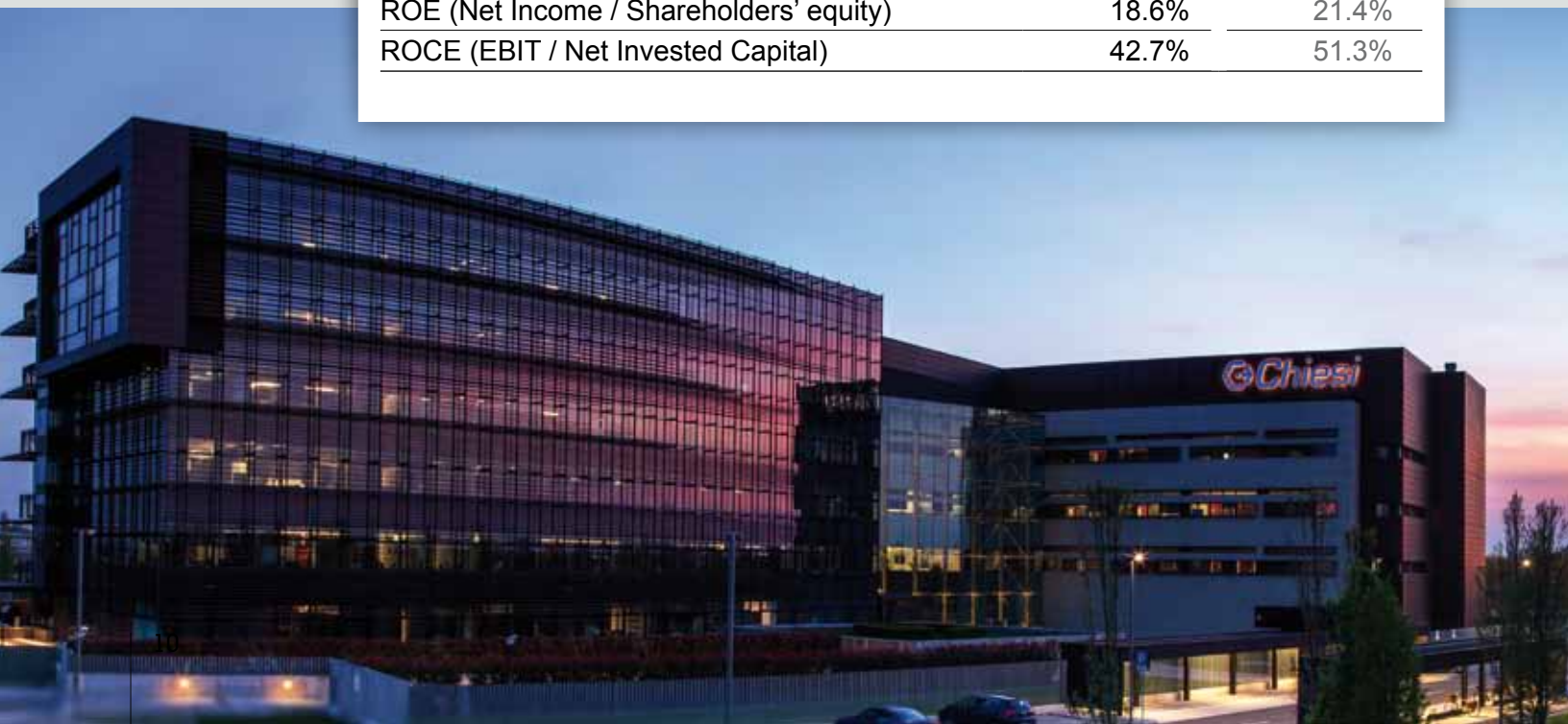
2014 Group Financial Highlights

(Value in Euro/000)

Operating Results	2014	2013
Sales & Revenues	1,341,651	1,237,283
Growth	*8.4%*	*11.8%*
EBITDA	372,385	360,426
% on sales and revenues	*27.8%*	*29.1%*
Net Income	192,748	183,752
% on sales and revenues	*14.4%*	*14.9%*

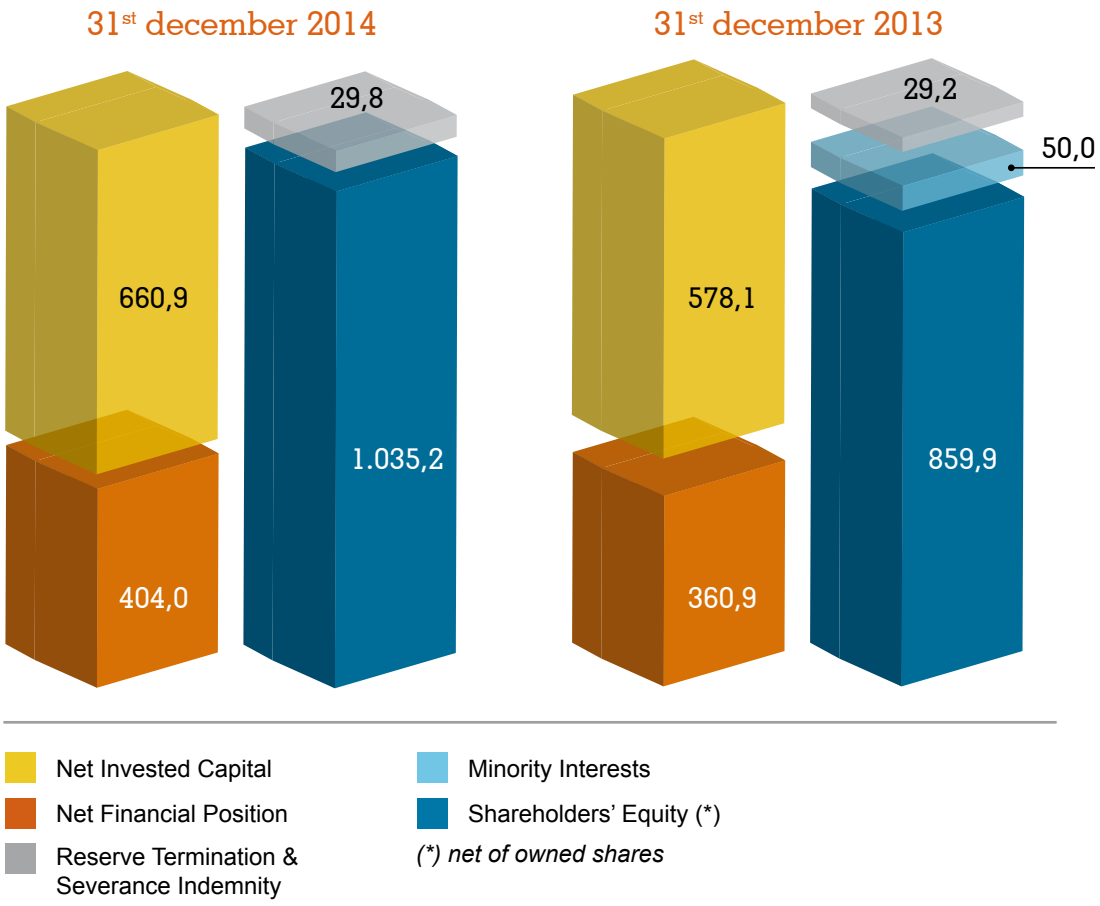
Other Information	2014	2013
R&D costs	235,540	167,722
% on sales and revenues	*17.6%*	*13.6%*
Capital Expenditure	176,350	118,482
- Mergers and Acquisitions	89,428	50,431
- Tangible and Intangible assets	86,922	68,051
of which R&D investments	*10,328*	*5,202*
Permanent staff	4,077	3,885
Temporary staff	325	298

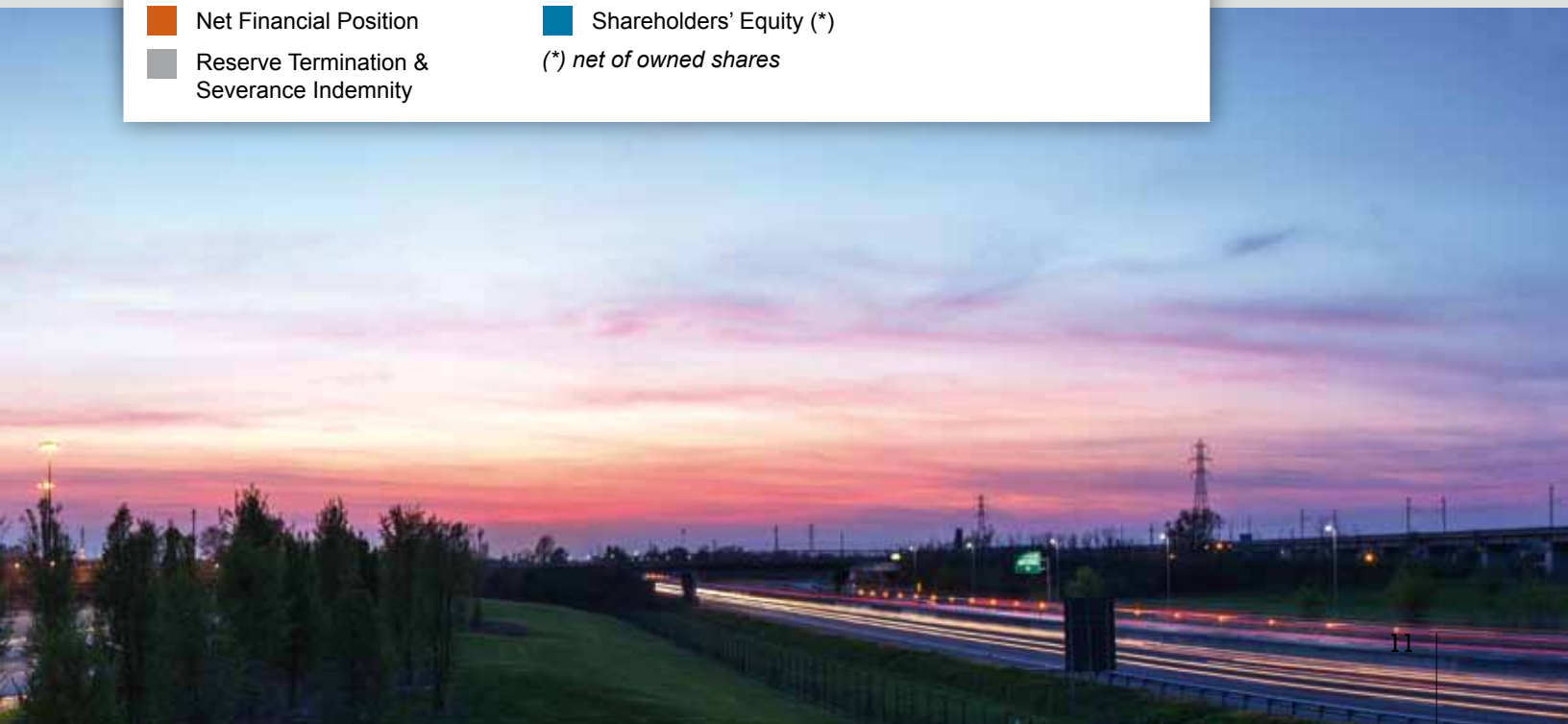
Ratios	2014	2013
ROE (Net Income / Shareholders' equity)	18.6%	21.4%
ROCE (EBIT / Net Invested Capital)	42.7%	51.3%



Group Financial Highlights

(Value in M/Eur)





Board of Directors

Alberto Chiesi

Paolo Chiesi

Alessandro Chiesi

Andrea Chiesi

Maria Paola Chiesi

Giacomo Chiesi

Ugo Di Francesco

Carlo Salvatori

Board of auditors

Giuseppe Piroli

Paolo Alinovi

Vincenzo Simonazzi

Executive Committee

Chairman
Alberto Chiesi

Vice-Chairman and R&D Director
Paolo Chiesi

Chief Executive Officer
Ugo Di Francesco

R&D Planning and Control Director
Andrea Chiesi

Strategic Planning Director
Maria Paola Chiesi

Group Human Resources & Organisation Director
Ugo Bettini

Corporate Drug Development Director
Mark Parry-Billings

Global Business Development & Licensing Director
Anton Giorgio Failla

Corporate Industrial Operations Director
Giovanni La Grasta

Corporate Finance Director
Danilo Piroli

Legal & Corporate Affairs Director
Marco Vecchia

Corporate Marketing Director
Giuseppe Chiericatti

Head of Region South Europe
Alessandro Chiesi

Head of Region North & Central Europe
Thomas Gauch

Head of Region Emerging Countries
Cosimo Pulli

Head of Region US
Ken McBean

#02

CHIESI 2014

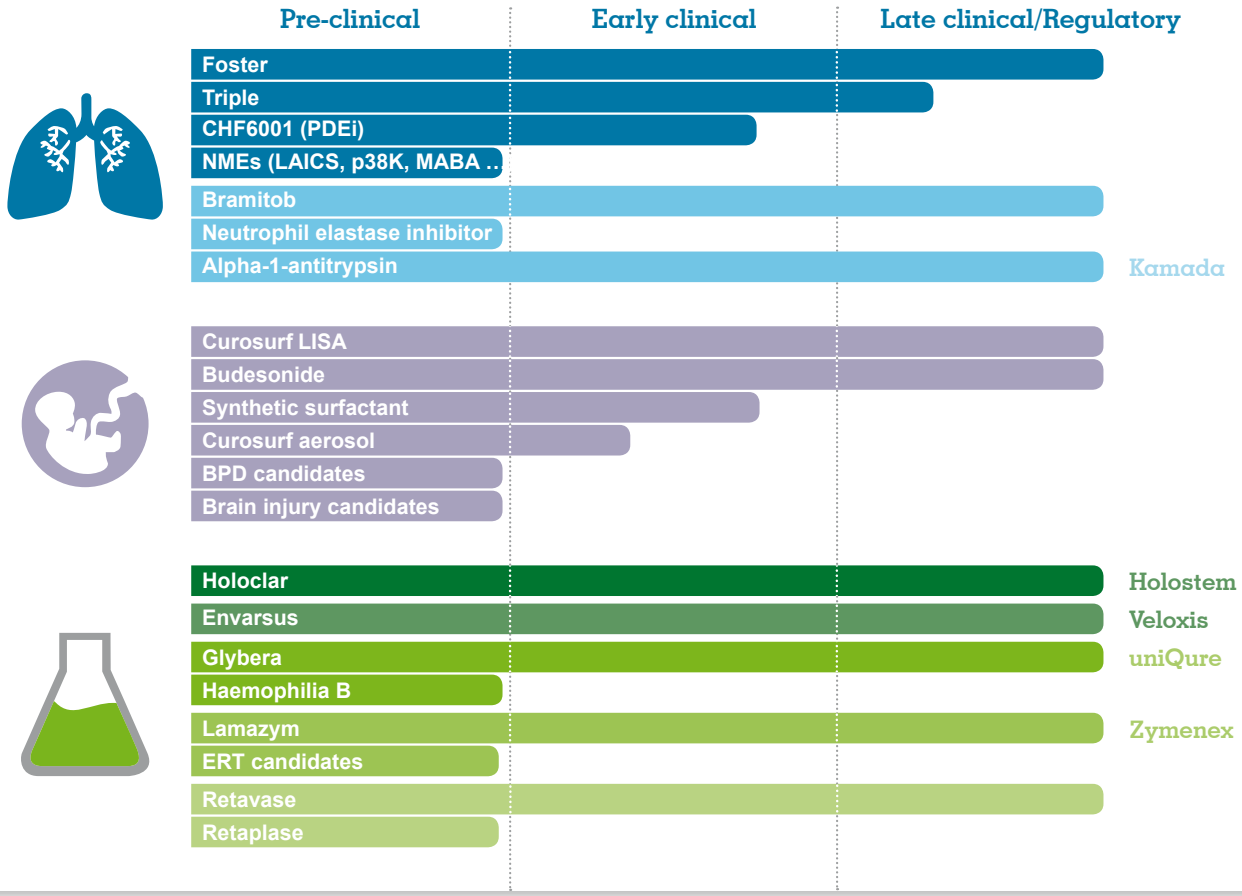
Research & Development Strategy

R&D is at the centre of Chiesi's future

Research & Development is at the centre of Chiesi's growth and will be even more so in the future. R&D productivity remains high with three separate marketing authorisations gaining approval and two further key marketing authorisation applications submitted in Europe in 2014. Overall, the number of programmes in our pipeline increased during 2014. At the end of the year there was a total of 41 projects in the pipeline: 7 discovery programmes, 18 projects in early development, 12 projects in pivotal trials or in the regulatory submission phase and for 4 projects post-approval R&D commitments were being delivered. This represents an overall increase of approximately 70% in the number of R&D assets, with positive progress demonstrated at all stages of the pipeline.

In 2014, approximately 17.6% of Group revenues were invested in R&D representing a total spend of € 236 million. Importantly, more than 70% of global revenues in the year continue to be generated by products delivered from the internal R&D pipeline.

Pipeline overview



2014 investments

236
Total spending in R&D (mio €)

equal to
17.6%
of revenues invested in R&D

Respiratory:
a series of positive milestones for this foundation of the R&D pipeline

Foster remains the main source of revenue for this therapeutic area, which is primarily driven by the pressurised metered-dose inhaler (pMDI) and dry powder inhaler (NEXThaler) product indicated for the treatment of asthma. Meanwhile, important progress has also been made in the pipeline with new dose strengths, dosage forms and clinical indications, which will further enhance the franchise. A number of critical business milestones were achieved during the year, notably:

- European approval was achieved for the treatment of COPD for the pMDI product, and the marketing authorisation application for the NEXThaler for COPD progressed with filing on schedule for the first half of 2015;
- separate and parallel marketing authorisation applications were filed in Europe for the pMDI and NEXThaler products, able to provide patients with more severe asthma with a high dose of inhaled steroid; approvals are expected during 2015.

The company continues to make market-leading progress in the development of its Triple inhaler. The product, which comprises a steroid (beclomethasone) and two different bronchodilators (formoterol and glycopyrronium) in a single inhaler, is being developed in both pMDI and NEXThaler formats, targeting the treatment of both COPD and asthma. The pivotal clinical trials made substantial and on-schedule progress during the year.

The proprietary pipeline of new molecular entities also progressed during the year, with the most advanced candidate (a novel inhaled phosphodiesterase inhibitor) advancing in clinical trials, and three novel anti-inflammatories (targeting inhibition of P38 kinase and neutrophil elastase, and a long-acting steroid) successfully entering full development. Positive progress was also made with novel drug candidates with dual mechanisms of actions, including the muscarinic antagonist beta agonist (MABA).

Neonatology: building on the legacy and commercial value of Curosurf

Curosurf, the animal-derived surfactant developed for the treatment of neonatal respiratory distress syndrome (RDS), forms the core of the Group's impressive platform in neonatology. Its activities in the field have focused on less invasive methods for the delivery of surfactant to the lungs of this delicate patient population. Important progress has been made regarding a proprietary less-invasive catheter for the delivery of Curosurf, including positive feedback from European regulators. Meanwhile, two distinct programmes are being advanced to deliver surfactant via aerosolisation to further enhance patient acceptability and the clinical outcomes of the treatment.

In addition to Curosurf, Chiesi has continued the development of a proprietary synthetic surfactant which achieved a very significant milestone in 2014 by successfully completing the clinical phase of the first clinical study in neonates with RDS.

Bronchopulmonary dysplasia is a disease with significant unmet medical needs affecting pre-term neonates. We were therefore delighted to see the presentation of the key preliminary results of a study with more than 800 neonates made by the European Consortium at the most prestigious neonatal congresses. The study demonstrated the benefits provided byBudiair for this disease, for which there are currently no approved treatments.

Neonatal brain injury is another condition for which there are currently no effective approved pharmacological therapies. As part of a joint initiative with the University College of London (UK), we have developed a high-dose intravenous formulation of melatonin, which has successfully entered key preclinical studies.

The field of neonatology remains a key focus for the business and the R&D effort, and a series of new opportunities are being evaluated.

Special care and rare diseases: a year of effective partnership

Two valuable and ground-breaking milestones were achieved in the year.

Early in 2014, European marketing authorisation approval was granted for **Envarsus**, which comprises a proprietary once-daily formulation of the immunosuppressant tacrolimus for prophylaxis of solid organ transplant rejection. The product is the result of a partnership with Veloxis, and the clinical indication was effectively extended during the regulatory review process to include both renal and hepatic transplantation.

Holoclar is a ground-breaking, tissue-engineered advanced therapeutic medicinal product, which has been developed in partnership with the subsidiary Holostem for the treatment of severe corneal injuries due to ocular burns. It is the first stem-cell product approved and filed in Europe, and at the end of 2014 it was approved by both the CAT (Committee for Advanced Therapies) and the CHMP, paving the way for formal European Commission approval in February 2015. This represents a true first for the field and for Chiesi's R&D.

Gene therapy represents another breakthrough approach in therapeutics, and through our partnership with uniQure, the Chiesi Group has taken a leading position in this field. uniQure has secured approval for **Glybera** and the process of access to the main European markets is now underway. The company is also successfully engaged with uniQure in the co-development of a targeted gene therapy for haemophilia B, which is soon to enter clinical trials.

Lamazym is the phase 3-stage asset which entered the R&D pipeline through the acquisition of Zymenex, the Scandinavian-based biotechnology company in 2013. It is an enzyme replacement therapy for a rare lysosomal storage disorder called alpha mannosidosis. The pivotal phase 3 study concluded during the year, and the data is currently being evaluated, as is the phase 3 readout from the inhaled alpha-1-antitrypsin asset which Chiesi partnered with Kamada.

Finally, the acquisition of Cornerstone Therapeutics, now Chiesi USA, Inc., during 2014, also added to the R&D pipeline to include two exciting opportunities stemming from a tissue plasminogen activator. The first leverages an FDA-approved biological product, Retavase (reteplase recombinant), which is indicated for use in the management of acute myocardial infarction. Significant progress towards market reintroduction was achieved in the year. The second developmental opportunity (CUSA 081) further leverages reteplase recombinant by targeting its use in the clearance of fibrin clots from various types of catheters.

Chiesi R&D people at the heart of Chiesi's growth

The exciting material progress made in the pipeline, evidenced not least by the continued filing and approval of marketing authorisation applications, would simply not be possible without the skills and continued dedication of our R&D team. There are a total of 514 staff members (398 corporate and 116 at the affiliates) in the R&D organisation, whose headquarters are at the purpose-built and fully-integrated R&D centre in Parma (Italy). In addition, the team also has important hubs in Paris (France), Chippenham (UK), Rockville (US), Lidingö (Sweden) and Hillerød (Denmark): these last two groups comprise the new colleagues from Zymenex. Projects are executed by cross-functional global teams in a matrix organisation.

Our goal is to enhance productivity further from our balanced and expanding pipeline to optimise delivery of innovative products to the commercial organisation and to patients.

Venture capital as an accelerator for the development of innovative therapies

by Scott F. Meadow

Clinical Professor Of Entrepreneurship | The University Of Chicago Booth School Of Business

Venture Capital firms are uniquely suited to the pharma process because they have learned to manage risk.

When a project is first organized it has *concept risk*. To move to the *growth-equity* stage, the project must have management capable of taking the project to an IPO or a sale. Also required for growth equity is evidence that the profit formula is proven and that the project is transitioning to a going concern, by insisting on a verifiable sales backlog of 18 months. In pharma, a project has earned growth equity status after completing phase 2 of the FDA continuum. Specifically with pharma projects, VCs have developed a business model around helping scientific researchers with limited commercialization experience find financing and expertise. These firms utilize advisors and entrepreneurs who have previous experience in commercialization to organize the project and interface with regulators. In the pharma VC world this involves financing the company through multiple phases of clinical trials, then selling the company to a larger concern that specializes in marketing that type of treatment.

Historically, the lack of institutional venture capital sources caused a financing gap in commercializing innovation. Today, the VC industry plays an important role in bringing potential new drugs to market by bridging the chasm between the grants funding basic research and taking potentially revolutionary treatments through the FDA or EMA approval process. The early Sixties marked the acceptance of alternative assets as worthy targets of investment and the emergence of institutional funding augmented traditional bank debt and investment from wealthy individuals and families to support new ventures. As higher-return/higher-risk ventures became part of an appropriately diversified fund, institutional venture capital began. Initially as a means of investing in *start-ups*, later financing *growth equity* and *near term liquidity projects*; by the mid-seventies, private leveraged acquisitions began. Investors supporting *start-ups* assumed *concept risk* and expected a high rate of return whereas growth equity project investors had only *execution risk* and took smaller returns. The early years saw an array of funds roughly $20 million in size where most projects were financed by a syndicate of 3 to 5 venture capital firms using the financial resources of the syndicate, and the collective contacts of the syndicate members.

In the United States, with the most mature entrepreneurial ecosystem, the syndicate structure has fallen away as venture firms have raised more money and the focus of individual firms has narrowed… and a venture fund that focuses only on products and services for the orthopedic market would be typical. In Europe, where there is a less-developed entrepreneurial ecosystem, there are more syndications and investing firms have a broader mandate… say all of healthcare.

Since drug development cycles often exceed 10 years, many pharmaceutical companies have developed large internal venture capital operations to deal with early-stage drug development; these now fund a significant fraction of drugs in early development. External venture capital firms are quite active through the out-licensing of drugs from large pharma. U.S. venture capitalists finance a project through stages 2 and 3 of the FDA process and then sell the drug to big pharma, which in turn distribute the new drug through a more comprehensive sales and marketing system.

An investment model is developing where institutional venture capitalists take on early-stage drug development by meeting with big pharma's internal venture capital funds to determine what early-stage "milestones" must be achieved by the biotech company for big pharma to bring the drug in house, continue development, and then out-license the drug to the external venture capitalists when the compound has reached stage 2. This system allows biotech venture capitalists to get involved in early drug discovery for 5 to 10 million Euros, whereas financing the entire drug development cycle exceeds their financial capability and time constraints.

Since 2000, increased specialization in the pharmaceuticals industry has seen larger firms becoming more risk averse and focusing on marketing and manufacturing while looking to purchase recently approved drugs to fill their product pipelines. Some VC firms like Domain Associates and Healthcare Ventures specialize in early-stage healthcare startups, while other firms such as Polaris Ventures and New Enterprise Associates have pharma investments as part of a diversified portfolio. The trend of pharma firms focusing on marketing and manufacturing while relying on scientists and VCs to deal with risks around regulatory approval should continue.
Plexxikon, founded in 2001 by two academics with a novel plan for developing new therapies, is an excellent example of how VC funding helps commercialize innovative therapies. They raised $50 million from venture capital firms in their first 2 years of operation, which allowed them to start the FDA approval process for several promising chemicals. One of the chemicals, Vemurafenib, received approval from the FDA in 2011. Immediately before final approval, Daiichi Sankyo bought Plexxikon.

This story has several hallmark characteristics of a VC-financed pharma deal. The founders were both academics who are still employed at their respective universities. Multiple VC firms, syndicating the deal to spread risk, provided knowledge of the FDA approval process, raised money from strategic alliances, and when the lead drug was nearing approval, sold the firm to a multi-national pharmaceutical company that could market it in multiple countries.

Business Development & Strategic Alliances

The role of Business Development at Chiesi is to complement internal R&D activities by acquiring new products, technologies and know-how developed outside the company.
The acquisition of projects and products in both the respiratory and neonatology fields (at any stage of development) is a particular focus.
In other therapeutic areas, where the company has yet to develop specific R&D skills, it is Business Development which looks for ways to acquire specific know-how (usually by company takeover) and also new products, although these products are exclusively at an advanced stage of clinical development.

This applies to products in special care, an area whose percentage of the current turnover the Group intends to increase from 21% to more than 30% over the next years.

In this regard two important agreements were signed during the year:

- the completion of the acquisition of Cornerstone Therapeutics, a Nasdaq-listed company of which Chiesi had been a major shareholder. The process was concluded in February 2014, when the definitive delisting of Cornerstone began, and the company is now the 26th affiliate entirely controlled. This operation has extended the global presence of the Company and represents a significant step towards strengthening its presence in the USA.
- An exclusive licensing agreement with Pharmaxis for the commercialisation of Bronchitol (mannitol) in the USA. Chiesi will finance the phase three clinical trial, in which the product is currently undergoing testing to obtain approval for the treatment of cystic fibrosis in adults. This agreement reinforces the Chiesi USA portfolio in the cystic area, which also includes Bethkis (inhalant tobramycin) and Pertzye (pancrelipase), both launched in the USA during the year.

A number of local agreements were also reached. These agreements concerned the co-promotion of several products in Greece, and the disinvestment of others in Brazil.

Special Care Objectives

30% Special Care share objective over the next years

21% Special Care area share of 2014 turnover

Main Products

Foster

A fixed combination of beclomethasone dipropionate (corticosteroid) and formoterol fumarate (a long-acting ß2-agonist with rapid onset of action) to be taken by inhalation.
Foster's key feature is its extra-fine formulation, which guarantees uniform distribution and high lung deposition throughout the entire bronchial tree, including the small airways.

Foster pMDI

The combination is available as a pMDI (pressurised metered–dose inhaler) in solution. This formulation based on Modulite technology allows one or two inhalations twice daily. Following its launch in Germany in 2006, Foster is now sold in over 45 countries worldwide, including Russia and China, and further launches are planned throughout 2015.
Foster can be administered also using the MART (Maintenance And Reliever Therapy) posology. In 2014, the product obtained the approval for the treatment of COPD (Chronic Obstructive Pulmonary Disease).

Foster NEXThaler

In 2013, the new extra-fine powder formulation started its commercialization in Germany, the Netherlands, Spain, and Italy.

Thanks to the innovative device NEXThaler, it is positioned as the most suitable treatment option to meet the needs of patients suffering from persistent asthma. In fact, thanks to the extra-fine formulation, the triple fulldose feedback system that guarantees the delivery of the full therapeutic dose and the ease of use Foster NEXThaler makes a significant step forward in the treatment of respiratory diseases.
In 2014, Foster NEXThaler was launched in many other countries, including Austria, Belgium, France, Brazil, Slovakia, Hungary, Slovenia and the UK. Foster NEXThaler will continue its commercial expansion through many other launches in 2015.

Foster

411 million €
turnover

21% growth on worldwide market share

present in more than
47
countries in the world

Curosurf

3 million
neonates treated since 1992

73%
global market share

present in over
80
countries around the world

Curosurf

An animal-derived surfactant for endotracheal administration, indicated in the prevention and treatment of neonatal respiratory distress syndrome in premature infants.
This syndrome was once the leading cause of neonatal death and is the result of lung immaturity in preterm infants.
Curosurf is an entirely natural surfactant, mainly composed of polar lipids and proteins. Since its introduction in 1992, Curosurf has been used to treat over 3 million newborns. It is the world's leading surfactant, with a 73% global market share, and is available in over 80 countries worldwide.

Atimos

This is a formoterol fumarate pressurised inhalation solution (pMDI) based on Modulite technology and indicated for the long-term symptomatic treatment of asthma and chronic obstructive pulmonary disease (COPD). Thanks to its rapid onset and long-lasting therapeutic action (up to 12 hours), formoterol is considered one of the best ß2-agonists currently available on the market. Atimos ensures optimal distribution of this active ingredient throughout the entire bronchial tree, including the small airways.

The drug is sold in all the main European markets and has proven to be well tolerated with respect to other DPI and pMDI formulations. The licensing of Modulite technology to Novartis confirms its efficacy.

Bramitob / Bethkis

This tobramycin formulation has been developed in a sterile inhalation solution for the treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF). The drug is available in mono-dose vials, to be administered twice daily in 28-day therapeutic cycles, alternating with a period of treatment suspension of the same duration. Bramitob improved lung function, reduced the need for and length of hospital stays, as well as the number of work and school days lost, and the need for intravenous antibiotics.

Bramitob is Chiesi's first product for cystic fibrosis and is registered and sold in 26 countries,including the USA where the product has been launched in November 2013 under the brand name Bethkis.

Brexin

Piroxicam ß-cyclodextrin (PBC) is a successful example of the clinical application of "guest-host" technology, which has been awarded the Nobel prize. The host is a starch derivative known as ß -cyclodextrin, which solubilises the piroxicam guest, a non-steroidal anti-inflammatory drug, thereby improving its pharmacological properties.

Piroxicam ß-cyclodextrin is mainly indicated for the treatment of painful and inflammatory conditions in patients with rheumatic diseases such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. The drug is sold today in Europe, South America, Asia and Africa.

Clenil

Clenil (beclomethasone dipropionate) is one of Chiesi's historical products and has become well established in the market since its launch in Italy in 1979. It is indicated for the treatment of asthma and other inflammatory and allergic conditions, and it comes in a range of formulations (pMDI, DPI, unit-dose vial for nebulisation, nasal shower pMDI).

The pMDI formulation uses Chiesi-patented Modulite technology. This has enabled the drug to achieve significant results in European countries, such as Italy and the United Kingdom, where sales and market share recorded consistent growth.

Clipper

Clipper (beclomethasone dipropionate) is indicated for the treatment of mild to moderate ulcerative colitis in its active phase. The drug is available in prolonged-release gastro-resistant tablets, to be administered once daily. The release profile of the product ensures targeted delivery of the active ingredient in the mucosa of the distal ileum and the proximal colon, where the inflammatory process develops. The drug exerts its anti-inflammatory effect locally and reduces to a minimum the systemic adverse events associated with corticosteroids. It is currently registered and sold in Italy, Belgium, Spain, and the United Kingdom.

Glybera

The value of Glybera (alipogene tiparvovec) lies in its ability to treat the underlying cause of LipoProtein Lipase Deficiency (LPLD) rather than provide symptomatic control.
Patients see a reduction in acute pancreatitis (-60%), relief from severely debilitating symptoms (pain) and sustained efficacy results. For prescribers Glybera is the only therapeutic option for LPLD as well as being the first gene therapy.
For the healthcare system the efficacy of Glybera impacts positively on healthcare budgets (reducing hospitalisation and ICU admission).

Envarsus

Envarsus (tacrolimus monohydrate prolonged-release tablets) is a drug indicated for the prevention and treatment of acute rejection in adult kidney or liver allograft recipients. For more than 20 years, tacrolimus has represented the main pillar in the immunosuppressive regimen that transplant recipients have to take for the entire life of their grafts. Envarsus is based on the Melt-Dose technology developed by Veloxis Pharmaceuticals. Thanks to this technological platform, Envarsus aims to address the intrinsic flaws of tacrolimus, improving the quality of life of its patients, and ensuring more stable plasmatic levels and a reduced total daily dose needed to achieve the same drug exposure. Thanks to its once-daily regimen, Envarsus simplifies the treatment regimen, helping patients improve their adherence to treatment. Envarsus is distributed by Chiesi throughout Europe, and in the US by Veloxis Pharmaceuticals. At the present time, the product is available in Germany and the Netherlands, and launches are planned for the rest of Europe in 2015.

Iperten /Vivace

This latest generation dihydropyridine calcium antagonist (manidipine), is indicated in the treatment of patients with mild to moderate hypertension. Unlike other traditional calcium antagonists and in addition to its antihypertensive action, manidipine also exerts specific effects aimed at reducing the total cardiovascular risk and improving the quality of life of hypertensive patients.
Today, it is available under different brand names in many countries: Italy, France, Tunisia and Morocco (Iperten); Brazil (Manivasc); Greece and Germany (Manyper); Spain (Artedil).
Vivace, fixed combination of manidipine and delapril, an ACE-inhibitor, fully developed by Chiesi, is indicated for the treatment of the hypertensive patients not adequately controlled on monotherapy. Vivace combines the therapeutic advantages of manidipine with those attributed to the ACE-inhibitor treatment in terms of efficacy, cardiovascular risk reduction and high tolerability. Vivace is currently commercialised in Spain and Greece and with the brand-name Hipertil in Brazil.

Peyona

A hospital use only orphan drug, registered in Europe and other countries such as China and Mexico, Peyona (caffeine citrate) is indicated for the treatment of apnoea of prematurity. This pathology is mainly due to the incomplete development of the centres in the brain that regulate respiration.
The clinical manifestation of apnoea of prematurity consists of spontaneous pauses in the normal respiratory rhythm, that can lead to dangerous hypoxic episodes in the neonate. Caffeine stimulates the respiratory centres in the central nervous system and has been shown to successfully decrease the incidence of apnoeic episodes, reducing the need for respiratory support and the incidence of bronchopulmonary dysplasia.
The drug is marketed in more than 20 countries.

Holoclar

This advanced therapy based on autologous stem cells can restore the eyesight of patients with severe corneal damage. Holoclar is the result of more than twenty years of research, conducted by a team of internationally renowned scientists in the field of epithelial stem cell biology aimed at clinical application. Holoclar is manufactured by Holostem Terapie Avanzate (Holostem Advanced Therapies), a spin-off of the University of Modena and Reggio Emilia and a subsidiary of Chiesi Farmaceutici.

Late-stage projects

Lamazym

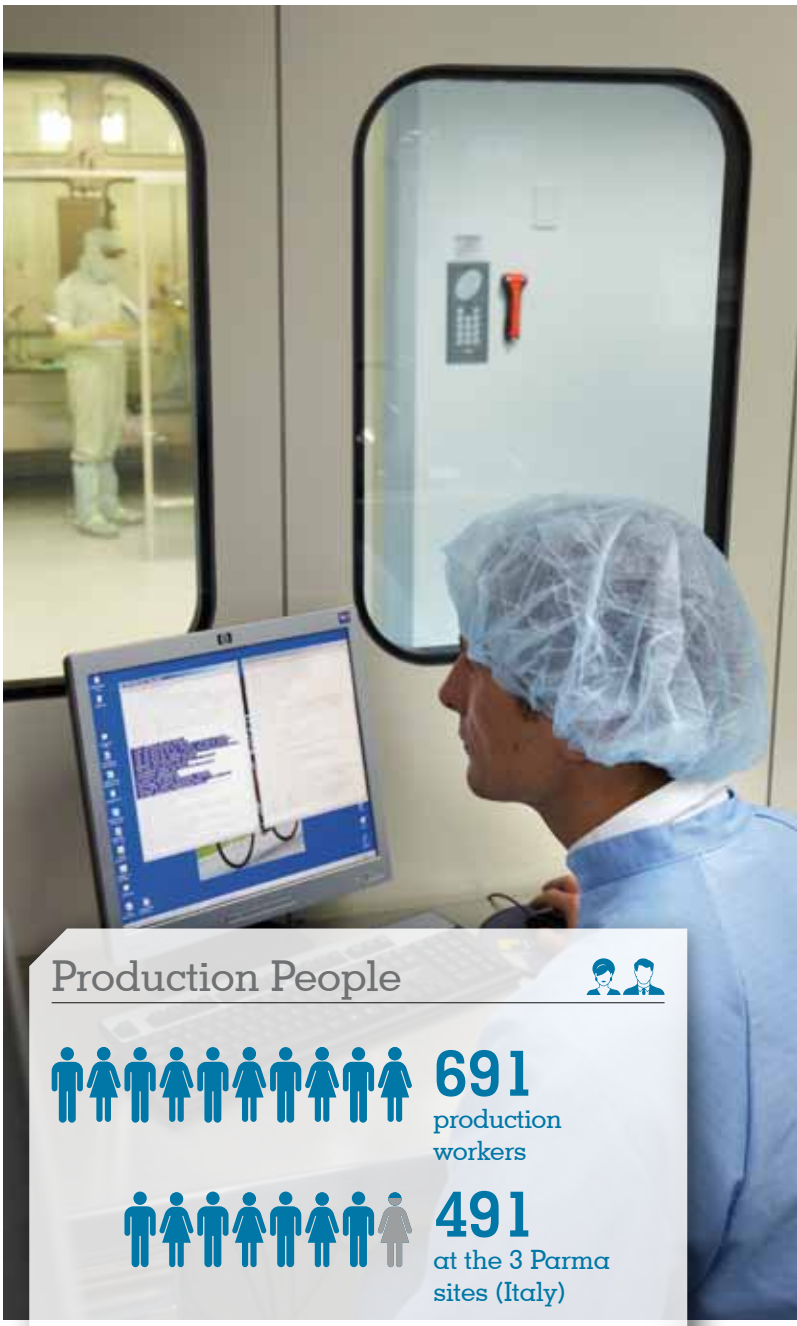
Lamazym is the first Enzyme Replacement Therapy (ERT) for alpha-mannosidosis, a genetic disease characterised by the progressive worsening of symptoms and mental/growth retardation. Patient prognosis is normally poor.
By replacing the missing enzyme, the underlying cause of the disease, Lamazym provides significant improvement in quality of life and clinical outcomes for the patient, which equates to providing added value for the healthcare system compared to current best practices.

Industrial Operations

Chiesi Group production involves 691 people and takes place at three sites: the Parma production facilities (Italy), with 491 employees split between the San Leonardo and via Palermo plants; the Blois-La Chaussée Saint Victor plant (France), which employs 75 people; the Santana de Parnaìba plant (Brazil), which has 125 employees.

Parma

The Group's most important production plant is also an international supply centre and exports to over 60 countries. The San Leonardo plant operates under the ISO 9001:2008 Quality Management System Certification and has passed many inspections carried out by the regulatory authorities of a number of countries, including the US Food and Drug Administration, the Canadian Therapeutic Products Program, the Chinese CFDA, Russian GMP & Quality Management Inspectorate, the Brazilian Health Agency A.N.V.I.S.A. and the Agenzia Italiana del Farmaco.A Health and Work Safety Management System complying with British Standard OHSAS 18001:2007 and an Environment Management system in accordance with ISO 14001:2004 have also been implemented and certified in this plant.
The correct application of international Good Manufacturing Practice standards, achieved using avant-garde technologies, represents the best way to guarantee worker safety and respect for the environment.
Annual production in Parma is in excess of 60 million sales units.
The San Leonardo production facilities prepare solid form drugs: tablets and powders for DPIs (Dry Powder Inhalers), solutions and suspensions either for pressurised MDIs (Metered Dose Inhalers) with eco-friendly propellants (HFA) or sterile unit-dose vials (UDV) with Blow-Fill-Seal technology (BFS) for use with a nebuliser.
Current 3-shift production capacity for sterile UDV nebulisation polythene vials stands at 210 million



Production People

691 production workers

491 at the 3 Parma sites (Italy)

75 in Blois (France)

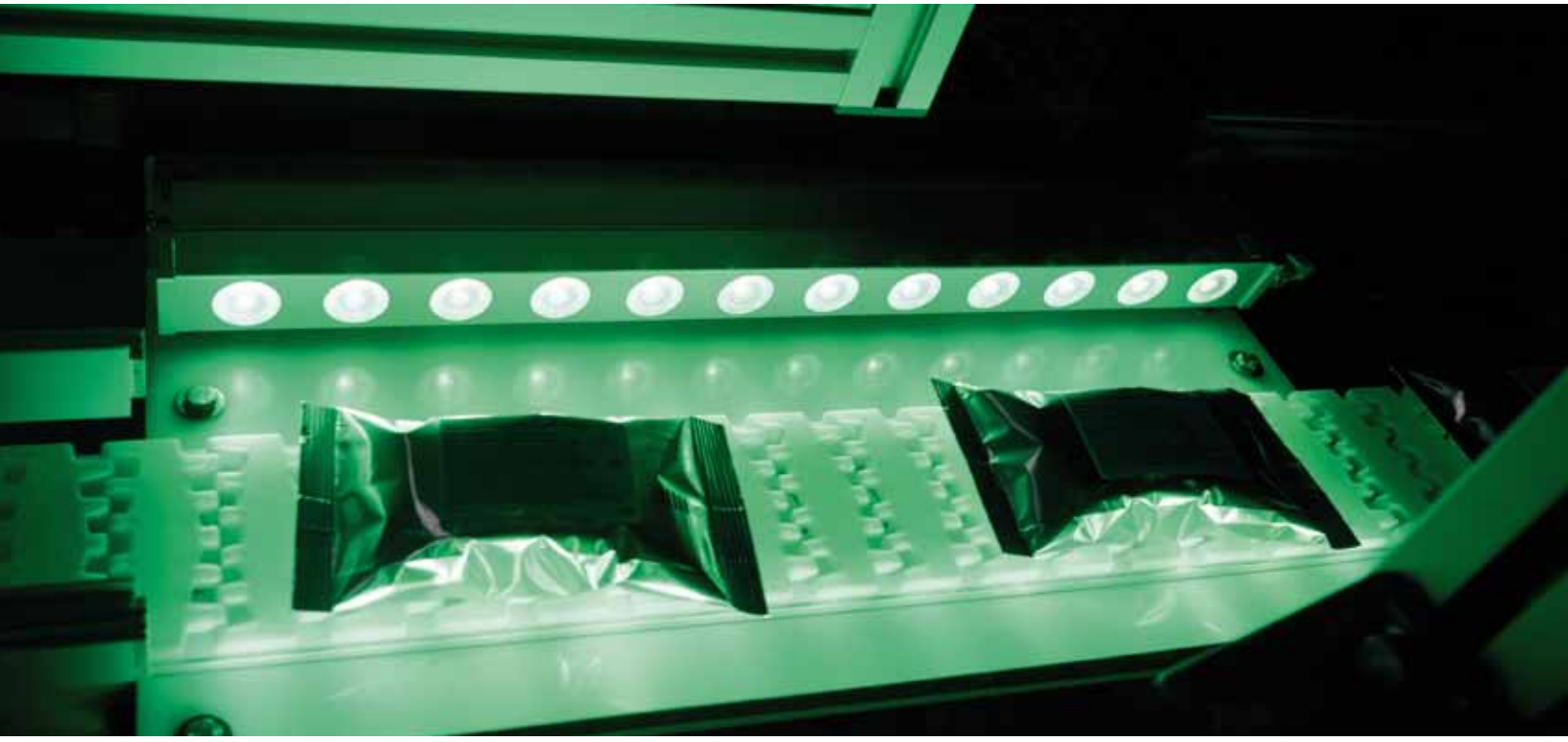
125 in Santana de Parnàiba (Brazil)

units (vials) per annum. MDI production capacity is in excess of 25 million canisters. The production facilities in via Palermo prepare vials of sterile suspension for endotracheal administration (Curosurf) and liquid form pharmaceuticals such as drops, syrups and nasal sprays. The Curosurf sterile suspension production department was expanded in 2006 and approved by European health authorities and the US FDA, and the plant supplying the active ingredient also increased capacity to over 530,000 units. Since then, new departments have also been created at the San Leonardo and Corlo plants, whose capacity now reaches over 1.5 million units.

In addition, the automatic filling and assembly line of the new Dry Powder Inhaler (NEXThaler), which also includes a packaging line with a capacity of 4 million sales units, is now running on a double shift.

Production and support processes (Cleaning in Place, Sterilising in Place) are managed and monitored by approved IT systems. In order to further increase the level of automation, Manufacturing Execution System (MES) type IT architecture has been put in place. The IT dispensing system has been linked to this, whereas the electronic batch record is already operative in almost all departments.

The Engineering department in Parma, which made a fundamental contribution to the creation of the new Research Centre and its approval from the various authorities concerned, has also completed the requalification of the via Palermo Site, the construction of new Curosurf departments for the active principle in Modena and for the final product in San Leonardo, and supported the French Plant in Blois in the construction of the new Dry Powder Inhaler (NEXThaler) Department.



Blois

Production at the Blois facilities stands at over 7 million sales units, which are mainly destined for the other affiliates in the Group. The French production labs specialise in capsule and tablet blister packaging and also in the final assembly and production steps for MDIs, which can then be deposited in the ample refrigerated storage facilities at the plant.
Blois is now also authorised to check and release batches; it is also equipped for direct distribution to the client for both the French and export markets.
Lastly, the new department for the production, packaging, checking and storage of the new NEXThaler powder inhaler has now been completed, and will assist the existing one in Parma.

Santana de Parnaìba

These facilities produce over 13 million sales units. The production lines prepare solid and liquid pharmaceutical forms, as well as solutions and pressurised suspensions for inhalation (MDI), formulated for use with eco-friendly HFA propellant.
Aside from the local market, these products are destined for those of the Group's other affiliates, including Italy and the UK, as a result of AIFA approval (Italian Agency for Pharmaceuticals) following regular inspections on site, and for export to licensees and distributors. The liquid line is currently undergoing a complete overhaul and expansion following the success of Rinoclenil in several countries worldwide.

Technological Support and Corporate Industrial Governance

The Corporate Manufacturing Technology, Corporate Engineering, Corporate Quality Operations, Corporate Logistics and Corporate HSE departments are able to support:

- Research and Development in scaling up developed products;
- production transfer between facilities both inside and outside the Group;
- partners producing directly with technologies patented by the Chiesi Group.

In addition, they are able to support:

- the due diligence activities for Business Development;
- the technological lifecycle management of existing products.

The Corporate Production function ensures that Lean techniques are extended throughout the Group's facilities to guarantee maximum productivity.
Lastly, Corporate Industrial Management Control oversees the Group's budget, product-costing and industrial reporting processes and also supports the economic assessment of the other corporate functions' activities, as well as managing production outsourcing.

Therapeutic Areas

Respiratory diseases

The company is fully committed to the treatment of pulmonary diseases, such as asthma and Chronic Obstructive Pulmonary Disease (COPD). To this end, we have created drug delivery technologies and devices to ensure efficient active ingredient distribution in the lungs.
Foster has been developed in order to provide an innovative treatment; its distinguishing feature is the extra-fine formulation, available both as pressurized Metered Dose Inhaler and Dry Powder Inhaler NEXThaler.
The formulation is able to release the active ingredient as extra-fine particles, guaranteeing the distribution of the drug throughout the entire bronchial tree, thus ensuring uniform treatment of inflammation and bronchoconstriction both in the central and small airways.
In addition to improving asthma treatment, the company is currently engaged in identifying new effective treatments for COPD, a condition characterised by a number of therapeutic needs that are as yet unmet. The pipeline consists mainly of projects designed to make significant advances in the treatment of asthma and COPD, thereby continuing to strive towards improving the quality of life of patients affected by these diseases.

Special care

Chiesi is also focussing its attention on the treatment and care of patients suffering from diseases treated primarily by specialists in the hospital setting and which are potentially life threatening. The commitment to this area is considered strategic for the Group's future and potentially of great social impact. Chiesi has a longstanding commitment to improving the standard of care for the management of preterm infants.
Curosurf has in fact become the international gold standard in the treatment of neonatal respiratory distress syndrome (nRDS). In addition, Peyona has been developed for the treatment of apnoea of prematurity, and new treatments are being investigated for other conditions, including bronchopulmonary dysplasia, affecting the long-term development of preterm infants.
Offering the medical and scientific communities new therapeutic options for the treatment of serious genetic diseases such as cystic fibrosis is another important focus of the company. The management of life long diseases such as cystic fibrosis is extremely difficult for both the patient and the clinical team. Together with the development of Bramitob launched in the USA with the brand Bethkis) and the acquisition of Hyaneb, both important products in the treatment of cystic fibrosis patients, Chiesi has been involved in the setting-up of

joint initiatives with physicians and associations to aid adherence and support the management of patients affected by this disease.
Thanks to Envarsus, indicated for the prophylaxis and treatment of acute rejection in kidney and liver transplant recipients, the Group has entered the world of solid organ transplants.

Rare Diseases

Patients with rare diseases typically face a number of issues, including a lack of access to correct diagnosis, information, scientific knowledge and appropriate quality healthcare. Chiesi is currently involved in four main areas: LipoProtein Lipase Deficiency (LPLD), an extremely rare disease with prevalence of 1:1,000,000; Limbal Stem Cell Deficiency (LSCD), a disease of the cornea caused by loss of limbal stem cells due to chemical and thermal burns; alpha-mannosidosis, a chronic, ultra-rare, genetic disease characterised by progressive worsening of symptoms and mental and growth retardation; haemophilia B, a disease caused by missing or defective factor IX, a clotting protein, and characterised by spontaneous and prolonged bleeding events affecting about 6,000 people in Europe. The current Chiesi Rare Disease franchise has 3 key products in its portfolio: Glybera, Holoclar and Lamazym. An additional project for the treatment of haemophilia B is in early-stage clinical development.

Global Marketing

Sponsorship

The Chiesi Group supports many scientific activities and actively participates in some of the most important medical – scientific con¬gresses in its therapeutic areas of interest.

RESPIRATORY AREA

European Respiratory Society (ERS)

The ERS is the leading organisation in its field in Europe. Its scope covers both basic science and clinical medicine. Chiesi is one of the major sponsors of the ERS congress, a meeting hosting over 22,000 physicians interested in the respiratory field.

American Thoracic Society (ATS)

The ATS mission is to improve health worldwide by advancing research, clinical care and public health in respiratory disease, critical illness and sleep disorders. Chiesi is a sponsor of the ATS congress.

Respiratory Distress Syndrome

International Workshop on Surfactant Replacement

The *International Workshop on Surfactant Replacement* can be considered one of the most important events sponsored by Chiesi. It is also commonly known as the "Curosurf Family Meeting" due the limited number of participants, who can attend only by invitation. The first edition of the Curosurf Family meeting was held in 1986, and over the years it has become a worldwide reference point for research in the field of pulmonary surfactants.

European Academy of Paediatric Societies Congress (EAPS)

This is the most important European paediatric meeting with a particular focus on neonatology. The sponsorship agreement includes, alongside the ordinary congress activities, the Robertson Award for Neonatal Lung Research and the Neonatal Lung Symposium, both sponsored by an unrestricted educational grant.

Corsi dell'European Society of Neonatologist

Chiesi is the only sponsor of a two-day post-graduate course prior to the EAPS Congress, an interactive course with top researchers, creating a partnership with the new generations of specialists.

SOLID ORGAN TRANSPLANT

European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Congress

ERA-EDTA is one of the most important scientific forums at international level aimed at supporting active discussion and the sharing of clinical experience related to dialysis and solid organ transplant. The two associations encourage the collaboration of the relative national societies to promote high-level scientific communication covering all fields of kidney research including renal physiology, hypertension, chronic kidney disease, dialysis, transplantation and its related complications.

Donorship

RESPIRATORY DISTRESS SYNDROME

The Curosurf Team also continued to support two projects in Cambodia and Burma in 2014:

- **Cambodia: Innocent Prisoners - *"The Knot" No-Profit International Association***

  The objective of the project is to assist pregnant women in prison and children who are living in prisons with their mothers because they have no better alternative.

- **Burma: The Health Paediatric Centre - *"A Helping Hand For Children" Italian No-Profit Association***

  The aim of the project is to provide free healthcare to the children of the Mobye Parish community in Myanmar (Burma), an area without hospitals within walking distance (the nearest hospital is several miles away).

High level donorship

Chiesi joins some of the most important global initiatives aimed at reducing the impact of the main respiratory diseases on a global scale.

- The **Global INitiative for Asthma (GINA)** works with healthcare professionals and public health officials to reduce asthma prevalence, morbidity and mortality.

- The **Global Initiative for chronic Obstructive Lung Disease (GOLD)** works with healthcare professionals and public health officials to raise awareness and improve the prevention and treatment of Chronic Obstructive Pulmonary Disease (COPD).

Patient Organisations

Chiesi Group supports the **European Federation of Allergy and Airway Diseases Patient Association (EFA)**, an international organisation that operates in the respiratory sector.
The EFA is a European network of patient organisations, prompted by the belief that its model is a more effective way of meeting the needs and safeguarding the rights of patients and their carers.

Human Resources

2014 activities

Over the year Group Human Resources concentrated its activities in three main areas: optimising the organisational structures, strengthening development resources and enhancing selection activities.

The organisational design evolves continually to respond to the expansion and geographical extension of the business. The Group People Development function in particular was created to meet the need for new skills more effectively, with the aim of enhancing selection, training and professional development procedures. The process of identifying the most suitable resources begins with an analysis of skills and organisational conduct, to successfully match the high demand for added-value internal resources and the offer of young talents and professionals with solid experience.

Within the development activities there has been an increase in the number of managerial growth programmes designed to respond to specific requests from the various departments. These customised coaching projects and activities supporting skills are set up once the organisation has expressed precise needs. At the same time, development training programmes on leadership and emotional/social intelligence have been created and integrated by means of the related interpersonal and emotional skills model.

Nevertheless, irrespective of the training tools used, the main aim is to further develop the learning system on bases common to the whole Group. Not only selection but also training has adopted appropriate quality indicators to ensure that the level of quality of this delicate process can be monitored.

The Talent Management project also forms part of the abovementioned design: in particular, it is based on a careful analysis of the business needs, thus laying the foundations for the development of the future skills system.

The Chiesi Academy continues with its Development for Executives And Leaders (DEAL) programmes, intended for senior managers, and those for Young Talents. Both development programmes have a significantly international focus, both in terms of the participants, who come from all over the world, and the teaching staff and centres.

The evolution of the business requires the international mobility of resources to accelerate, both to consolidate the wealth of knowledge and professional experiences and to ensure greater added-value career paths. The six international mobility procedures activated in 2014 demonstrate this, and now total nineteen in eight different countries, as do

the 18% of searches for international positions assigned to internal candidates.
Chiesi Farmaceutici Italy, and the affiliates in France, Spain, Germany, the UK and Poland have received the Top Employer award in their respective countries following a complex evaluation process; this joint achievement has enabled the Group to win Top Employer Europe for the third time.
There have been a number of innovative developments in People Management activities, as has emerged from the recent survey entitled People Voices. Among the initiatives implemented by Chiesi Farmaceutici Italy, there are two worth highlighting: the Flexible Benefits programme, an innovative tool that supplements salaries and can be tailored to individual needs, thanks to which the Group can provide goods and services for production workers, office staff and intermediate managers, and Smart-working, currently being piloted to look into the possibility of carrying out part of the job (one or two days a week) from home or from another location. These initiatives demonstrate the attention dedicated by the Group to its people; this is also confirmed by the fact that since 2014, the variable remuneration system Management by Objective includes as one of its parameters the evaluation of People Management.

2015 programmes

Development activities represent one of the current year's biggest commitments both for Group Human Resources and all the affiliates. Their involvement is intended to promote the professional growth of all the organisation's resources, so as to respond to the increasingly challenging demands from the evolving business also in completely innovative areas, such as advanced therapies, which involve key business processes: from research to the clinical development, regulatory activities, market access, production and commercialisation of the drugs.
In response to this growing demand, the Talent Management project continues with the simultaneous creation of a skills model based on an analysis of the organisational needs over the next five years and that of skills profiles and professional families. The integration of these two components will also lead to the launch of specific development programmes and a system to harmonise job titles. This will permit the Group to define a common language for all its affiliates, supplying the elements needed to define the characteristic skills for each professional family.
The Group has also signed an agreement with Ernst & Young to set up a database which will enable it to create a map of the open positions throughout the Group and cross-reference them with the profiles of the people who intend to take part in this kind of experience, so as to fully exploit the Group's International Mobility programmes.

Information & Communication Technology (GICT)

In addition to guaranteeing the Group's operational continuity and setting up international projects requiring a considerable organisational effort, e.g. the implementation of SAP at the affiliates in France and the UK, GICT carried out a radical restructuring process over the course of 2014 with the aim of reorganising its activities at global level. The project is intended to ensure that the GICT organisational model, the company's growth and recent changes within the IT field are all aligned with one another. Some of the most important developments have been the progressive implementation of SAP at all the affiliates, the gradual centralisation of important application platforms including production planning, the management of laboratory analyses (Laboratory Information Management System), pharmacovigilance, quality management systems and establishing standards for the technological infrastructure.

The logical model on which the new GICT organisation is based will require it primarily to try to align with the Group's business model, regardless of the technology it uses. At the same time, its internal processes are designed to remain constant as far as possible, so as to guarantee the continuity of IT services.

The elements constituting the new organisational model represent a decisive shift towards key ICT processes (Demand, Solution and Delivery), the increasingly marked separation between Solution and Delivery and the strengthening of relations with the business functions. GICT has based the development of this model on international standards used widely throughout the sector. In particular, the project referred to EUCIP regarding the definition of ICT professionals' skills and COBIT for the processes characteristic of the IT function and the theoretical and practical tools relating to these processes. The validity of the new model, which has been operative since January 2015, can be evaluated on the basis of its capacity to respond effectively to the changes in the company's business. The new ERP now operating at two of the larger affiliates, France and the UK, has begun to benefit significantly both in terms of shared language, which ensures that the business performance at the different affiliates can be compared, and standardised processes and reports.

Going back to the projects set up over the year, the SAP roll-out programme played a key role: aside from the launch in France and the UK, the implementation process in Brazil got underway last year and is scheduled for launch in the second quarter of 2015. Once again at Group level, two other initiatives have been introduced to complement SAP: a review of the application platform which draws up the budget and reporting (PRS) and the implementation of a Group Treasury model.

2015 also promises to be a year packed with programmes that will make a considerable impact on both GICT and the Group as a whole: SAP roll out in Germany and Spain, an updated Intranet, a new electronic Document Management System, the extension of regulatory activities to all the Group's products, the creation of a single employee records database at Group level, a talent management system and the extension of Trackwise for quality processes.

In line with the new organisational model, these activities will be carried out keeping local solutions to a minimum and prioritising those common to the Group.

1 European Certification of Informatics Professionals. Si veda in proposito http://www.eucip.com

2 Control Objectives for Information and related Technology. Si veda in proposito http://www.isaca.org/cobit/pages/default.aspx

A Short History of Pharma Digital Communications Pioneering

by John Mack, aka "Pharmaguy"

Pharma Marketing Pundit & Critic, Blogger & Publisher of Pharma Marketing News

A pioneer stands out from the crowd. That's why I wore a garish yellow and black Hawaiian shirt at an October, 2009, "un"-conference of bloggers, pharma marketers, and consultants who were anticipating the November, 2009, FDA public hearing on the Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools. Just a few months prior the FDA sent out 14 warning letters that threw pharma marketers into a tizzy and prompted many "un"-conferences and other discussions.

Although these meetings produced no guidelines for pharma, I decided to recognize social media pioneers in the pharmaceutical industry who were blazing trails without any guidance from FDA. Thus was born the first Pharmaguy Social Media Pioneer Award, which was handed out in 2010[1]. The recipient was the Digital Strategy and Social Media Manager at a UK pharmaceutical company. The award was the Hawaiian "shirt off my back."

What did this social media manager do that was so pioneering?
He was responsible for launching the first pharma disease awareness Facebook page to allow comments without prior review. All comments were posted first and then reviewed afterward.
Since then, a lot of water has flowed under the pharma social media bridge and many pharma social media pioneers have come and gone. The FDA has even issued long-awaited social media guidance and the industry is currently interpreting and commenting upon those guidelines.

But if today's pharma marketers and communicators do not wish to repeat the mistakes of others, they need to know more history than what happened beginning in 2009. They need to go back to the Web 1.0 era; 1996 to be precise. In October of that year the FDA held its first 2-day public hearing to evaluate how "the statutory provisions, regulations, and policies concerning advertising and labeling should be applied to product-related information on the Internet and whether any additional regulations, policies, or guidances are needed."

In attendance at that seminal FDA meeting were many of the people directly responsible for creating the "Medical Internet" at that time. It included representatives from the pharmaceutical industry, advertising and marketing industry, medical associations and publishers, patient advo-

1 "First Pharmaguy Social Media Pioneer Award given to Janssen's Alex Butler"; http://pharmamkting.blogspot.com/2010/10/first-pharma-guy-social-media-pioneer.html

cacy groups, physicians, website developers, and other government agencies such as the Federal Trade Association. Some of these pioneers later founded the Internet Healthcare Coalition, which in 2000 published the eHealth Code of Ethics for developing credible, quality health information on the Internet[2]. The code included these guiding principles:

1. Candor & Trustworthiness
2. Quality
3. Informed Consent, Privacy & Confidentiality
4. Best Commercial Practices
5. Best Practices for Provision of Health Care on the Internet by Health Care Professionals

Although these guidelines are focused on what we now call Web 1.0, they are as applicable in today's Web 2.0, social media world as they were "back in the day."

The disease awareness Facebook page that received the first Pharmaguy Award was shut down in 2012. The company cited as a reason its inability to moderate posts that mentioned specific drug names or talked about the efficacy or side effects of a specific treatment. Indeed, moderation of social media conversations is an ongoing problem for the regulated pharmaceutical industry, which must be careful not to promote or even appear to promote its products off label.

Meanwhile, other pharma social media pioneers have shown the utility of Twitter for communicating with healthcare professionals. At least one pharmaceutical company routinely hosts TweetChats focused on specific medical conditions. Despite the regulatory challenges posed by such activities, these chats are successful, both in terms of delivering value to stakeholders and to the company, while remaining compliant with existing laws and regulations. More importantly, the company wrote a "playbook" that provides detailed insights for planning and delivering successful pharma TweetChats. For their effort, the authors of the playbook received the 5th Annual Pharmaguy Social Media Pioneer Award[3].

Other pioneers have learned from their mistakes and moved on to master these new communication channels to engage patients. And some are sending their employees to "school" to learn about the challenges and opportunities that social media offer.
Although many trails have been blazed, there will always be a need for pioneers to show the way to new territories of communication. These days, the newest digital/social media territories yet to be fully explored by pharma pioneers are mobile, "gamification," wearables, and the Internet of Things (IoT).

Many pharma pioneers have already ventured into the mobile space with some success. As expected, however, there are also failures, most of which have to do with quality, accuracy, and privacy best practices issues that we thought were codified way back in 2000.

The jury is still out regarding wearables and the IoT. While many marketers in general believe these technologies have a place in their strategies, most of the hype probably comes from the anticipation of the Apple Watch. "Everyone wants to know what's happening with wearables," said Manhattan Research's Monique Levy[4]. "Unless you're working in the innovation team and you're thinking five years ahead, I wouldn't stay up all night worrying about wearables. You need to worry about smartphones and what you're doing to be mobile optimized". Seems like good advice to me. Happy trails!

2 "e-Health Code of Ethics"; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1761853/

3 "Boehringer Ingelheim Receives the 2014 PharmaGuy™ Social Media Pioneer Award"; http://www.pharma-mkting.com/news/pmnews1309-article02.pdf

4 "@MonLey Advises #epharma to Forget About Wearables, Focus More on Mobile."; http://sco.lt/4ulmIT

#03

CHIESI WORLDWIDE

South Europe

North & Central Europe

Emerging Countries & International Commercial Operations

Our Offices

South Europe

Pharmaceutical Division Italy

For the ninth consecutive year, the Pharmaceutical Division Italy has performed beyond market levels, thus confirming itself a leader in the respiratory sector.
Chiesi's level of growth in the retail market recorded by IMS Health (Sell-in data by revenue) stands at +0.6%, in a market currently at -1.3% compared to 2013.

In addition to product quality and brand value, this year has seen an innovative approach to the market. The Italian affiliate was expanded with a team of commercial agents in pharmacies and its portfolio with the Line Extension project to extend product lines dedicated to the respiratory area. This resulted in the entire organisation developing both ethical and OTC products and also identifying new partners for new formulations and medical devices through licensing activities.
Key activities for the year included improving and standardising processes, to ensure invested resources are used more effectively.

In 2014 **primary care** continues to perform well with a growth of 3.3% by revenue compared to 2013, which was already a record year. Chiesi is a leading company in the respiratory sector, both by volume and revenue. In December, Foster gained more than a 20% market share for the first time, in what is today considered one of the most competitive sectors in the national pharmaceutical arena. This result is due to the launch of the powder formulation and the continued growth of the spray formulation. The respective market shares of Clenil A and Fluibron A, already in excess of 50%, have continued to grow.
The year was also marked by the relaunch of Rinoclenil, which went from less than 1% of the market share to almost 5%. The high penetration of generics in the cardiovascular sector has generated a less positive trend in the area, although our products have managed to reach the year's targets.

Special care also closed the year on a positive note with an increase of 2.1% by revenue. Flagship product Clody is once again confirmed market leader in the musculoskeletal area for injected bisphosphonates with an increase of 10.1%. The neurological products, and Jumex in particular, continue to achieve one of the best performances in the reference market, whereas the results in the gastroenterological area have felt the effects of strong competition and the reduced competitiveness of our products, caused by a cut in the number of formulations offered. An increase of 7.9% for Curosurf means that the neonatology area remains an area of major importance for Chiesi, in spite of falling birth rates and hospital healthcare spending cuts. In thalassemia, a 4.6% growth rate was recorded, thanks to the consolidation of the Ferriprox range.
Plans for 2015 include two projects: increasing promotion in the musculoskeletal and gastroenterological areas, and entering into a new special care area thanks to Envarsus, a therapy for the prevention of liver and kidney transplant rejection.

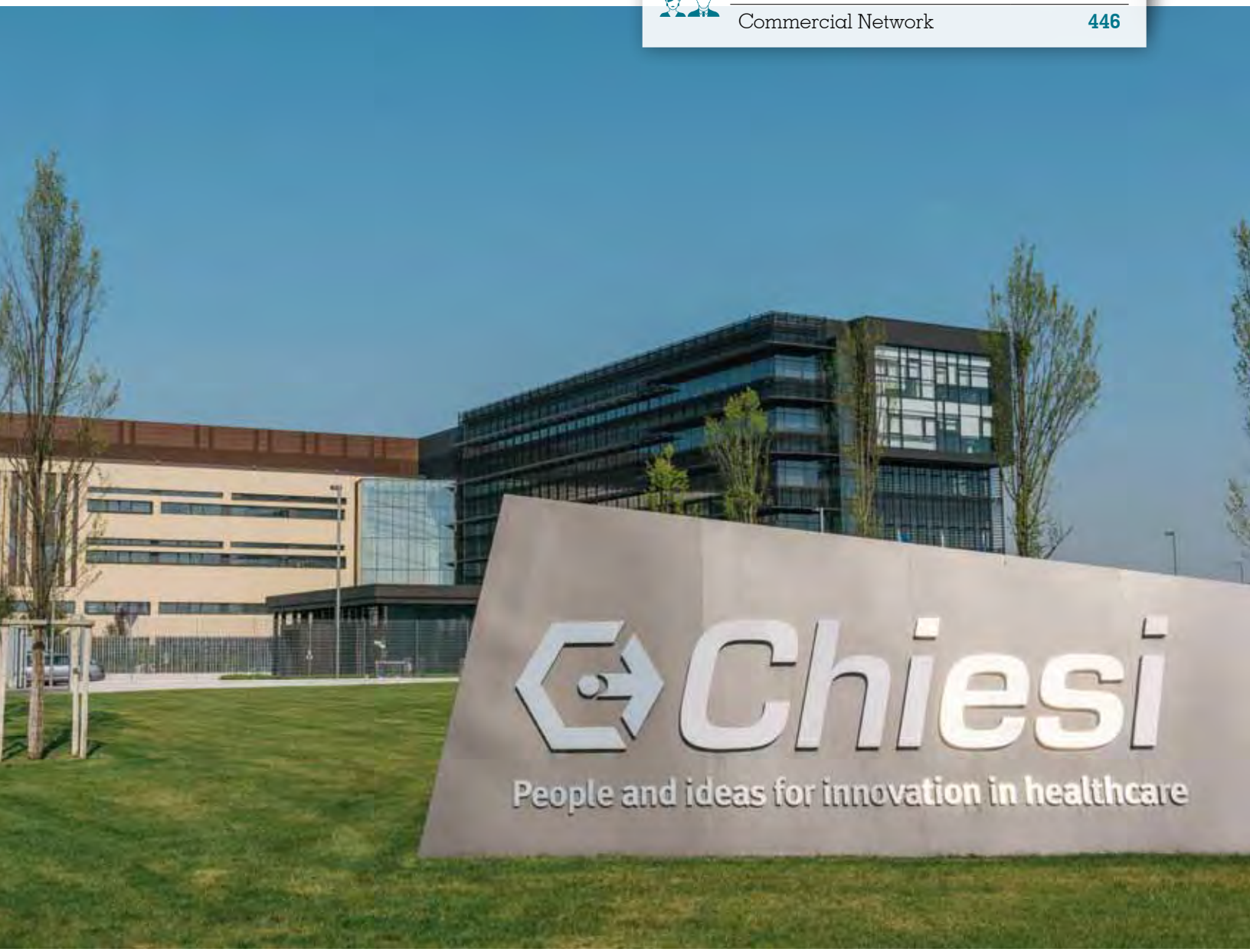
For **Sales & Distribution**, 2014 has been a year of evolution.
On the organisational side, a line of commercial agents in pharmacies was set up; in the portfolio, with the launch of the first products in the "Line Extension" project on Clenny and Fluibron.
The year's negative result, - 6.0% by revenues, is mainly attributed to the overall sales of products in the cardiovascular area, whose markets saw an unexpected degree of contraction, yet where Chiesi maintained if not improved its level of competitiveness in terms of market share.
Excellent results were achieved in the consumer

area. Clenny A, which moved from seventh to third place in the nebuliser device market, is now in second place and only a few thousand units behind the leader in this sector. As already mentioned, 2014 saw the launch of the first products in the "Line Extension" project: Fluibron Spray Gola, with an excellent sales performance and Brexidol 4 patches, which contributed to achieving an increase of 48.4% by revenue for the Brexidol brand.
2015 will see the development and completion of the first phase of the "Line Extension" project with new product launches in the Clenny and Fluibron lines and the activation of innovative and communication projects in support of both consumer and mature products.

These achievements are the result of a close-knit team able to develop and support innovation through the proactive contribution of all its members.

Italy

Domestic direct Sales (K€)	296,190
Variation versus 2013	4.5%
Human Resources	1,620
Commercial Network	446



Chiesi France

In 2014 the French affiliate reported 109.5 M€ of revenues, of which 103.2 M€ in France and 6.3 M€ in Maghreb. Corporate products have represented more than 90% of the total sales.

France

Domestic direct Sales (K€)	103,194
Variation versus 2013	2.1%
Human Resources	320
Commercial network (direct + interim)	159

The affiliate has consolidated its position in the respiratory domain thanks to the launch of Nexthaler in September. Innovair/Next reported 50 M€ sales in total, taking first place in the ranking of best-selling products on the local market. Beclospin (16 M€) and Curosurf (14.4 M€) represent the 2nd and 3rd brand of the affiliate on the French market.
2014 was also the year of two main events: the SAP go-live and Blois manufacturing plant extension. SAP successfully went live with the support of the Corporate team without any significant business or operational issues.
For the NEXThaler extension, the manufacturing area is operational and the validation batches being processed. The project, which will be finalised in 2015, has a total budget of 22 million Euro.
An important training plan for the employees has been deployed, and seven employees have joined the plant staff.
In 2015 in spite of a depressed market, the affiliate has shown renewed growth. The gain of market share is mainly due to the extension of the Innovair product range. The year will also be important in preparing the launch of Envarsus and planning a stronger presence in Special Care. The activities concerning the rare disease therapeutic area will also increase, thanks to a well established roadmap for market access.

Chiesi Spain

Chiesi Spain's results for 2014 have been outstanding despite a challenging year for the Spanish pharmaceutical market, which remained flat throughout the whole year: revenues reached nearly €82.5 million, including direct sales and royalties and fees, with an increase of 15% and climbing positions in the market.
The affiliate has maintained its structure with around 235 employees, 75% of whom are sales force distributed in three business units: retail, focused on general practitioners and specialists; Special Care, focused on hospitals; and consumer health, focused on pharmacy sales.
In terms of the Primary Care, 2014 was a very good year for Foster with a growth rate of 24%. Despite the aggressive cardiovascular market and high number of generic brands in Spain, Vivace and Prevencor are maintaining their position in the market, thus making Chiesi a reference company in the cardiovascular field.
The special care unit focuses its promotion on the hospital market with products like Clipper, Bramitob,

Curosurf, Peyona and Hyaneb. Despite the difficulties being experienced by the hospital market in Spain, the Special Care team has closed the year with an increase of 8.7% on The previous year's sales. Clipper has achieved its target, Curosurf grew by 6.3%, and Peyona and Hyaneb were up by 44.7% and 76% respectively.
It was also a good year for the consumer healthcare business unit, which promoted the company's OTC products in an increasingly competitive local market. Flogoprofen grew by 15% and Norlevo by 16%. The Business unit has achieved its goals and represents 21% of the affiliate's total sales.
These results based on our people drive Chiesi to continue working on developing its team and fuel the change it intends to bring to its business.
With a well-defined strategic plan, the affiliate is ready to move forward to achieve its goals for 2015, investing resources in its talents and developing innovative solutions to increase its market share, presence and leadership in OTC, respiratory

Spain

Domestic direct Sales (K€)	77,234
Variation versus 2013	13.4%
Human Resources	233
Commercial Network	180

Chiesi Hellas

Despite another challenging year for the local economy, Chiesi Hellas continued its successful performance, maintaining its turnover in a contracting market thanks to key products like Foster and those in neonatalogy and special care.
Co-promotion activities with local partners once again contributed to its results by absorbing all the losses from the cost containment measures in the healthcare sector. At the end of the year the affiliate was 35th in the IMS ranking with Foster classified among the top 80 pharmaceutical products in the country. Moreover, mature brands like Manyper and Becloneb grew further to contribute significantly to the affiliate's budget, while the special care and neonatal portfolios also performed well in their relative market segments.
In 2014 Chiesi Hellas started a new HR training programme for its entire staff, an initiative named "entrepreneurship", aiming at achieving a greater performance and better results in the coming years.

Greece

Domestic direct Sales (K€)	17,211
Variation versus 2013	-1.8%
Human Resources	65
Commercial Network	40

Chiesi Belgium

2014 was a momentous milestone for the Belgian affiliate. The launch of Inuvair NEXThaler, contributing to the innovative image of Chiesi as a respiratory partner in a DPI-driven country, was the driving force behind the sharp increase in the Inuvair® market share in the fixed-combo-market, reaching more than 20%.

This, together with a strong performance from Curosurf and Clipper – the latter showing double digit growth (13%) for the 4th year in a row – allowed Chiesi Belgium to further build on the previous year's success showing once again a robust growth rate (24.9% compared to the previous year), reaching a turnover of €18.3 million.

Chiesi Belgium has acquired a Business Knowledge function to provide support and advice to the business functions. In addition, a number of new initiatives such as the non-promotional development approach offering medical information to clinicians and other external medically-related personnel were launched.

Furthermore, Chiesi Belgium reinforced its image as a key player in the Belgian respiratory market and is therefore well appreciated by healthcare professionals and specialists in particular.

Its 2015 aim – to lay the foundations for a mature growing company – blends perfectly with the initiatives of global integration through close collaboration with corporate functions and the development of people and talents. Initiatives in digital and multichannel communication and the development of added-value patient services as well as other structural improvements are high on the Belgian team's list of priorities.

Belgium

Domestic direct Sales (K€)	18,322
Variation versus 2013	24.9%
Human Resources	34
Commercial network (direct + interim)	35

North & Central Europe

Chiesi Ltd, United Kingdom

2014 saw the UK affiliate achieve the new total sales target £121 million – and this was net of the PPRS 3.74% rebate mechanism.
The result enabled the UK affiliate to climb further up the all-UK pharmaceutical company league table to attain 16th position on a MAT basis and 14th position during the month of November (IMS BPI)
Sales growth was again largely driven by Fostair, which showed a continued growth rate in excess of 40%. Fostair sales benefitted from the successful launch of the COPD indication for the pMDI device, coupled with the later launch of the Fostair NEXThaler for the treatment of asthma.
Clenil continued to be a key contributer to the overall company sales with a sales achievement in excess of £51.3 million and a record 76.5% market share.
Contribution from local products remained significant with strong growth continuing from some key important products.
The Special Care Business unit had another successful year with significant results achieved by Curosurf, Bramitob and Peyona.
In addition to planning the launch of a new product for the beginning of 2015 in the kidney and liver transplant area, the UK affiliate prepared to move into the Rare Disease area with some key launches planned for the present year.
The affiliate also plans to relocate to a new, larger purpose-built head office in Manchester, which will be able to accomodate the needs of a rapidly growing affiliate.

United Kingdom

Domestic direct Sales (K€)	149,887
Variation versus 2013	15.4%
Human Resources	202
Commercial network (direct + interim)	163

Chiesi Germany

2014 was again a good year for the German affiliate: revenues have increased, in particular by continued growth of the brand Foster and in the field of neonatology.
Chiesi Germany once again increased its market share (+ 8.4%) and reached 5th position in the global German respiratory market.
A high number of competitors entered the respiratory field in 2014, but Foster was still able to achieve a double-digit growth rate. An important event was the launch of the COPD indication the our product.
In September an additional contract sales organisation began successfully promoting Foster NEXThaler with selected general practitioners who have so far not been met.
In the Special Care area two new products were launched in 2014: Envarsus and Glybera. The first marks Chiesi's entry into transplantation: a high-

Germany

Domestic direct Sales (K€)	110,740
Variation versus 2013	6.3%
Human Resources	206
Commercial network (direct + interim)	201

ly-specialised and sensitive therapeutic area demanding a significant degree of scientific support for transplant physicians. Glybera, the first gene therapy approved in Europe, requires a totally new approach with regards to national market access and reimbursement.
One of the main objectives for Chiesi Germany 2015 will be the preparation of the Holoclar launch following marketing authorisation, again a totally new therapeutic area.
To support an even more valid marketing and sales model, the affiliate has created a business unit as well as a state-of-the-art CRM-system. Along with other affiliates, Chiesi Germany will implement the SAP system at the beginning of 2016, and the preparation for this event will be another focus for this year.

Chiesi Central Eastern Europe

The Chiesi Central Eastern Europe Group with its headquarters in Vienna, is the regional structure representing the Chiesi corporation in Central and Eastern European Countries (except Poland and Russia), the affiliates within the Commonwealth of Independent States (CIS) and Mongolia. From Vienna the whole group is serviced in logistics, regulatory, medical and financial matters. Aside from Chiesi's corporate products in respiratory disorders, rheumatology and neonatology, the regional portfolio is well-established in anaesthesiology, intensive care, rare disease medicines and the treatment of addiction. The company is actively looking for further in-licensing products for selected business areas.

Austria & CEE

Sales in Austria and CEEC Market (K€)	68,716
Variation versus 2013	9.9%
Human Resources	182
Commercial network	95

Chiesi Austria

Chiesi Austria manages its portfolio in Austria through two business units, in primary and special care. The primary care unit has a strong focus on respiratory diseases with its flagship Foster, now also available as Foster NEXThaler. In-licensed from Grifols (Spain), the product Prolastin offers an important treatment for a rare genetic disease which also affects the lungs. Formoterol MDI completes the portfolio. The special care unit has a broad product range in intensive care medicine, neonatology (Curosurf and Peyona) and Bramitob for cystic fibrosis. Chiesi Austria contributes with more than 30% to the overall turnover of Chiesi Pharmaceuticals GmbH.

Chiesi Bulgaria

This affiliate was established at the beginning of 2008. Its main products are Curosurf and Foster. For the latter the reimbursement for the COPD indication and the launch of Foster NEXThaler are further important milestones. Flamexin was launched at the beginning of 2006 and is maintaining a strong position in the anti-rheumatic treatment.

Chiesi Czech Republic

The respiratory products, especially Foster which was launched in 2011 under the brand Combair, represent the key successes in the portfolio in the Czech Republic. Hospital products Bramitob (and Curosurf, together with Sufentanil, Midazolam and Fentanyl, represent the traditional special care line.

Chiesi Romania

In the past, Chiesi Romania succeeded in managing a couple of difficult years for the pharmaceutical industry due to very unfavourable changes implemented by the government and a shortage in liquidity in the healthcare system. The portfolio was mainly based on Curosurf and Flamexin. At the end of 2014 reimbursement was obtained for Foster MDI, which was launched at the beginning of 2015.

Chiesi Slovakia

The affiliate, which has been operational since 2004, has always achieved considerable success over the years. Since the launch of Foster in 2007, Chiesi has maintained a significant market share, also when compared to other affiliates. In 2013 the Foster formulation containing 180 puffs was introduced, followed in 2014 by the launch of Foster NEXThaler.

Chiesi Slovenia

This well-established affiliate (1998) has its most important area of activity in the respiratory area with Foster and Atimos. Local products such as ReVia (an anti-addiction drug) and Midazolam Torrex are also main contributors to sales in Slovenia. In 2014, the launch of Foster NEXThaler and the reimbursement of the COPD indication are marking further development in the pulmonary segment.

Chiesi Hungary

In spite of the difficult pharma-economic situation in Hungary the business was successfully developed in 2014, mainly based on the respiratory franchise (Foster MDI, Atimos), now further completed by the launch of the Foster COPD indication and Foster NEXThaler. The affiliate also maintains a strong position in the anti-rheumatics segment (Brexin), while Curosurf, Bramitob and Midazolam are the pillars in the special care area.

Chiesi Pharmaceuticals Export Area

This area, managed by the export division, covers the former Yugoslavian Countries (except Slovenia), the Baltics, the CIS (except Russia) and Mongolia. Local partner companies are providing service for registration, marketing and distribution. This region represents some 20% of the total revenues for Chiesi Central-Eastern Europe, and is considered a major source of dynamic development for the future.

Chiesi Netherlands

It has been another successful year for the Dutch affiliate, leveraging upon further growth and acceptance of the Foster portfolio with its COPD indication for pMDI and the launch of Envarsus for immunosuppression in the field of organ transplants. It was once again a year of growth, both in terms of people and sales.

The Netherlands

Domestic direct Sales (K€)	30,799
Variation versus 2013	30.7%
Human Resources	50
Commercial network	28

With 49 employees the Dutch affiliate has become one of the 10 biggest contributing countries within the Chiesi Group. Revenues have grown by 30.5% compared to the previous year to reach €30.8 million Euro.
This achievement saw the Dutch affiliate break into the top 30 pharmaceutical companies in the Netherlands.
The results have been driven by sustained growth rates for the major brands in the respiratory (Foster, NEXThaler, Atimos, Bramitob) and neonatal (Curosurf, Peyona) therapeutic brands. In 2015 the affiliate will continue to focus on increasing its presence by expanding its current portfolio and launching Glybera and Holoclar.
Building the Chiesi brand in the Netherlands, by corporate social responsibility activities and added-value services and programmes (Chiesi College) for all relevant stakeholders, will contribute to the reputation and acceptance of the company and its current and future brands.

Chiesi Poland

The Polish affiliate, which was established at the beginning of 2005, mainly focuses on developing the position of hospital products (Curosurf and the anaesthetic portfolio). Bramitob has been subsequently added to the special care product range. Since 2009 pulmonary products, starting with Budesonide, followed by Atimos and Fostex, have boosted the development of the Polish organisation. In 2014 Fostex 180 was the main driver of business with a contribution of 72.7% to total sales and a 21.0% market share.
In spite of the aggressive generics promotion on the combo market the company achieved an excellent performance with a 20.4% growth rate, as the 5th fastest growing company according to IMS, a rate three times higher than the Polish pharmaceutical market in 2014 (+6.16%).
In the same year, the affiliate was certified as the TOP Employer in Europe and Poland and has obtained the prestigious Forbes Diamond Award as one of the fastest growing medium-sized companies between 2010-2012.

Polonia

Domestic direct Sales (K€)	27,234
Variation versus 2013	13.3%
Human Resources	99
Commercial network (direct + interim)	86

Emerging Countries & International Commercial Operations

Chiesi Russia

The growth of the Russian pharmaceutical market has slowed due to the negative economic situation in the country, demonstrating a reduction of 3.6% (by volume) and +9.3% growth (by revenue) compared to 2013. Within this framework, Chiesi Russia has maintained the last year results with +1.2% growth in local currency turnover.
Curosurf is confirmed as the gold standard and maintained its leading position in Russia with a 95% market share among surfactants. It is included in Russan clinical guidelines as the only product that can be administered with a less invasive approach.
Sales in the respiratory portfolio continue to grow. Although Foster was not listed in the federal reimbursement system, it was included in 30 regional reimbursement programmes and reached +19% compared to 2013 .
In 2014 Chiesi Russia secured the registration of Vasobral providing health authorities with the results of a local clinical study and a comprehensive pharmacovigilance report for the last 5 years.
The affiliate has also obtained the distribution license needed to take over Vasobral and market Atimos and Clenil Jet, which will be produced in Russia with the biggest national manufacturer Pharmstandard.

The main objective for 2015 is to succeed with double-digit sales growth in all the relevant segments with the new launches of Hyaneb and the Foster MART and COPD indications. Chiesi Russia continues focusing on the development of Foster sales in regional reimbursement channels and maintaining Curosurf's leading position through an ongoing Russian educational campaign.

Russia

Domestic direct Sales (K€)	30,459
Variation versus 2013	-15.5%
Human Resources	106
Commercial network (direct + interim)	74

Chiesi Brazil

The affiliate had an excellent performance in 2014, once again outperforming the Brazilian retail pharmaceutical market, which according to IMS was up by 13% in 2014 to reach R$65 billion sales. In the same period, Chiesi Brazil achieving a growth of +14% and reached 46th position in the ethical market. Chiesi Brazil's overall growth, considering retail and hospital channels, reached 12.3% in local currency.
Throughout the year, our promoted products showed a strong demand growth rate, mainly due to Clenil HFA, Clenil A, Manivasc and Fostair. By consolidating Curosurf's leadership, the affiliate reached a 70.2% market share and was up by 12% in net sales on the previous year.
Fostair pMDI continues to grow above market levels: while the growth of the segment stands at 4.1%, Fostair pMDI grew 28% by volume. (units, MAT Dec 2014).
Fostair DPI was launched in August with great ex-

pectations among physicians due to the excellent patient acceptance of the NEXT powder inhaler product. Fostair DPI already contributes to the result of the brand with a 36% growth rate by volume (units, MAT dec'14).

Brazil

Domestic direct Sales (K€)	64,944
Variation versus 2013	3.1%
Human Resources	312
Commercial network	135

In addition, Chiesi Brazil launched two new line extensions: Clenil HFA 200mcg, which offers convenient dosage to patients and complies with the lower dosage recommendation made by Brazilian guidelines and GINA; and Forten, now with 20 units, to strengthen the brand and offer better treatment adherence.
Another important achievement was the 20% expansion of the field force, aimed at focussing on the "Farmacia Popular" programme.
In 2015 the affiliate will continue to focus on increasing its sales to outperform the Brazilian Pharmaceutical Market. This will be achieved by expanding its key products, Fostair and Clenil HFA, and by launching new products in the neonatology and respiratory line.

Chiesi Mexico

Established in 2012, Chiesi Mexico has consolidated its presence in the neonatology field with Curosurf and Peyona.
In 2014 Chiesi covered all the thirty two Mexican states with a new special care field force structure. This was instrumental for the penetration of Peyona, which is now market leader in the country. Mexico is one of the most important markets for the product at Group level.

Mexico

Domestic direct Sales (K€)	8,742
Variation versus 2013	27.9%
Human Resources	32
Commercial network (direct + interim)	46

A great milestone was the launch of the respiratory line. To launch Innovair (Foster) Chiesi Mexico hired new employees, mostly for the marketing, sales and medical areas.
By the end of the year, the product, which went on sale in July, gained a 3% market share.
The second largest market in Latin America, after Brazil, Mexico is mainly driven by generic growth, and Innovair is a key product, as its pricing strategymakes it affordable for a significant segment of the population.
The positioning of Innovair in the Mexican market will be the affiliate's main focus for 2015 and represents a significant challenge due to new competitors and price erosion on respiratory products following the generification of major brands.
In the coming years Chiesi intends to introduce its full respiratory pipeline and also expand its neonatology portfolio with local business development activities.

Chiesi Pakistan

In spite of the difficult conditions, Pakistan's pharmaceutical market was able to maintain double-digit growth (11.8%) whereas the affiliate managed a remarkable sales evolution of 14.7%, allowing Chiesi Pakistan to improve its market share of 0.67%.
The integrated efforts of the field force, and the marketing and management teams, combined with the support of other central operational units in the company led to the successful realisation of the organisation's commercial and financial objectives. The corporate brands of innovative products played a pivotal role in the success of the affiliate.
Brexin is the top contributor to affiliate sales and maintained and further strengthened its position in the relevant market with over 2 million units sold.
Foster, the affiliate's flagship product, has gained excellent results, successfully reaching a 34.5% growth rate and securing a market share of 17.5%.
Once again in the respiratory area, the affiliate achieved outstanding sales results and substantial evolution for key products such as Clenil Aerosol (+26%), Clenil Compositum Aerosol (+34%), Atem UDV (+29%) and Rinoclenil 100 (+315%).
Neonatology, another developing area for the affiliate, has shown a consistently improving sales trend for Curosurf , which reported 12% growth.
The affiliate's objectives for 2015 include increasing its sales volume by exploring new therapeutic areas to ensure the growth and sustainability of the organisation.

Pakistan

Domestic direct Sales (K€)	13,391
Variation versus 2013	14.7%
Human Resources	168
Commercial network	135

Chiesi Turkey

Chiesi Turkey continued to grow in 2014 and became the 5th fastest growing multinational company among the top 50 players, with 19% sales growth in local currency.
The Primary Care business unit had a successful year with 13% growth, driven by the 8% growth of Foster and 16% growth of Rinoclenil. Foster has the only positive growth rate among its major competitors and has outgrown the market. Rinoclenil has had the highest growth rate among the top five in its area.
The year was also made special by the introduction of marketing projects and multi-channel communication tools for the primary care unit. European COPD approval and the Future trial was used as a leverage communication and a satellite symposium was carried out with over 500 participants.
In the special care business unit, Curosurf generated outstanding growth , gaining an 80% share in the surfactant replacement market, and aims to reach 85% in 2015. The special care team will further extend its contribution to the affiliate by entering into cystic fibrosis with Hyaneb.

Turkey

Domestic direct Sales (K€)	27,090
Variation versus 2013	5.8%
Human Resources	149
Commercial network	116

Chiesi Turkey has embarked on an initiative to expand its field force and marketing effectiveness by using new CRM and CLM systems.
Receiving GMP level-1 priority from the Ministry of Health for Envarsus will accelerate the time to market for the product and help Chiesi Turkey maintain the growth momentum in the near future.

The Cyladol co-branding project with a local firm continued to deliver results: Cyladol sales have in fact tripled.
Following the recent approval of the MART indication in asthma, 2015 will be an ambitious year for Foster, which aims to gain market shares both in asthma and COPD.

Chiesi China

The Chinese pharmaceutical market continued to grow in 2014 (+12% on 2013), but the rate was slower compared to that of the previous year due to national and provincial price containment measures. Chiesi outperformed the market with a growth rate of more than 40% in local currency.
This result was driven mainly by Curosurf and Peyona, confirming Chiesi as the reference company in neonatology:
Curosurf reaffirmed its leadership by growing faster than the products in its class and achieving a 74% market share.
2014 was dedicated to the market access process for Peyona, a challenging task in China. The product is now listed in 250 new hospitals and its sales exceeded RMB 15 million, making China the Group's largest Peyona market.

China

Primary Sales (K€)	44,664
Variation versus 2013	67.2%
Human Resources	136
Commercial network	98

Foster and Clenil also made good market access progress. They were launched in the fourth quarter of 2013 thanks to Chiesi's joint venture with Eddingpharm, whose team negotiated the provincial biddings and obtained hospital listings for the two products in the formularies of 274 hospitals.
Over the year, the affiiate continued to invest to strengthen its organisation with the aim of sustaining its expansion in the coming years:

- new offices were opened for the company's headquarters in Shanghai and for its regional offices in Beijing and Guangzhou
- all the functions were strengthened and the marketing team was extended at regional level to support field force sales and enhance the execution of regional programmes
- a new Customer Relationship Management system was introduced together with improvements in territory management systems for field Sales.
- new programmes for training and compliance were developed and implemented.

In line with these developments, Chiesi now aims to cover the emerging regions within China, by doubling its special care unit over the coming 18 months.
The respiratory joint venture will also gradually extend its regional reach in line with its performance in achieving the necessary broader market access for Foster and Clenil.

Chiesi USA Inc.

2014 was a solid year for Chiesi USA with annual net sales of $215.8 million. This performance resulted in a ranking of 112th in the list of annual sales by US pharmaceutical companies. 2014 performance was led by Cardene RTU and Zyflo, which both exceeded $78 million in net sales. Curosurf also demonstrated good performance with sales of more than $44 million. The cystic fibrosis franchise had year-over-year growth of over 300%.
In late 2014, Chiesi Group signed a licensing agreement with Pharmaxis covering certain rights to Bronchitol. Under the terms of this agreement, the affiliate will commercialise Bronchitol in the US, and it looks forward to completing the required clinical work, obtaining FDA approval, and, ultimately, expanding its cystic fibrosis portfolio with the launch of Bronchitol.
In 2015, we intend to continue driving the growth of our product portfolio, advancing our internal pipeline projects, and providing new opportunities for growth through successful merger and acquisition activities.

USA Inc.

Domestic direct Sales (K€)	160,285
Variation versus 2013	11.4%
Human Resources	139
Commercial network	60

International Commercial Operations

International Commercial Operations Division (ICO) is the department that focusses on expanding the commercialisation of Group products around the world.
Its mission is to develop the business in all available markets by deploying Chiesi's proprietary portfolio, improving performance in each market and setting up the most appropriate business model.
Over the years, ICO has acted as the incubator for a number of country operations, which have now become fully-fledged affiliates.
Amongst its success stories there have been Turkey, Mexico and, more recently, China.
Working in around 50 countries with almost 70 partners, it often acts as the ambassador of the Company's entrepreneurial and innovative spirit around the globe, as well as the support function to enable partners to successfully launch Chiesi's products in their territories.
This means that ICO has several projects on the go at any one time, and has the opportunity to see the product launches on an almost constant basis.
2014 has been no different, with the Division focussing on the expansion of the corporate products throughout the world. Key events for the year were the launch of Curosurf in The Dominican Republic, Guatemala, Honduras, El Salvador, Nicaragua and the United Arab Emirates. Curosurf remains the number one product by revenue for the Division, and continues to grow in existing markets and penetrating new ones.
Foster has also been launched in new markets, namely The Philippines and Indonesia, and continues to go from strength to strength, taking second position by revenue within the Department.
The product showed notably interesting performances in South Korea, Taiwan, the U.A.E. and Tunisia.
Our Nordic affiliate launched Peyona in Sweden, Finland, Denmark and Norway. The picture was completed with the launch of Clenil in Hong Kong.

2015 is again going to be another full year for ICO, with several launches planned in different territories across the five continents, and the move of the Division to new offices in Parma, once again confirmation of the importance given by Chiesi to company internationalisation.
None of this would of course be possible without the help of many people in the corporate structure, especially our regulatory, legal and logistics colleagues, and the support and efforts of the many distributors around the world who are key to the success of the Group products in their respective markets.

Sales to International Distributors

Sales to distributors (K€)	**51,156**
Variation versus 2013	**5.6%**

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#04

SOCIAL RESPONSIBILITY

Corporate Social Responsibility according to the Chiesi Group

Business ethics and governance models

Quality, environmental protection and safety

Other CSR initiatives

Added-value distribution

The Chiesi Foundation

Corporate Social Responsibility according to the Chiesi Group

An analysis of the economic results, investments and growth characterising business processes cannot provide us with a complete picture of the Chiesi Group's activities. A number of activities concern aspects which either directly or indirectly contribute to turning the abstract concept of Corporate Social Responsibility into concrete actions.
The environmental protection and safety programmes and numerous initiatives that the staff at the head office and the affiliates create for the benefit of the people working for the Group, particular patient categories and local communities, all demonstrate the ability to use the available resources to the full. The aim of these initiatives is to help those in greatest need and promote safe and environmentally-conscious behaviour. Their geographical distribution highlights the way in which the impact of Corporate Social Responsibility has been felt throughout the affiliates.

An analysis of the added-value distribution illustrates the activities to which this value is directed. One particularly interesting statistic concerns the investment of around €11.5 million in training activities, confirming the central role attributed to personal development by the Group. Economic resources used in this way translate into professional and organisational skills which enhance the company's potential for development.

Social Responsibility

11.5 million €
investment in training
for the Group's people

The numerous activities carried out by the Chiesi Foundation are widely discussed in the final chapter and underline a commitment to scientific research, the training of young researchers and international cooperation for the sharing of medical and technical knowledge. The Foundation, which celebrates its tenth anniversary in 2015, represents in an increasingly systematic and defined way the lasting and tangible commitment to the world of no-profit.
The growing resources and knowledge dedicated to Social Responsibility reflect the way the Group is evolving both from a geographical point of view and that concerning new therapeutic areas. At the same time, they also demonstrate the intention to interact constructively with all the Group's stakeholders to contribute to safeguarding the environment, developing new knowledge to improve healthcare and helping the socially disadvantaged and those in need

Business Ethics and Governance Models

As the Group continues to develop, so its business becomes increasingly complex. This means that business ethics are being applied in a greater number of increasingly diverse areas.
Chiesi adopted a Code of Ethics and Conduct in 2002 as a tool for defining the commitments and responsibilities with which the company's activities should be carried out. From that moment on, the attention dedicated to this topic has constantly grown, and in particular in 2012 when the Group adopted the Chiesi Group Guidelines on Ethics & Compliance with the main aim of aligning governance processes and systems and ensuring that all the risks are adequately detected and managed.

Working method

The concepts and legislative references concerning the procedures adopted for the management of business ethics are subject to periodical review.
In particular, the process followed for this activity entails:

- *benchmarking the relevant legislation and best practices*;
- a prevention-oriented approach by means of a governance system at Group level;
- collaboration, involvement and where necessary, support for the affiliates in correctly interpreting and implementing company regulations.

In addition, in the countries which have adopted anti-corruption legislation, non-compliance risk assessment activities are carried out with the help of specialised consultants and the assistance of the local management.

2014 activities

Chiesi has maintained a considerable level of commitment in these areas and, in line with the plans made, the implementation of the Group Guidelines on Ethics & Compliance has been extended to the foreign affiliates operating in Slovenia, Romania, Belgium, Greece, Pakistan, Turkey, Mexico and the USA (a new legal entity resulting from the completion of the Cornerstone Therapeutics takeover).
The Corporate Compliance Committee, whose job is to support the affiliates in correctly interpreting and adopting the guidelines and monitoring implementation, has interacted with them.

In those countries where specific anti-corruption legislation has been implemented, the affiliates have carried out risk assessment activities to further evaluate the level of adequacy of governance processes and systems, with the support of external consultancy companies and under the Group's central coordination.

In the Spanish affiliate a decision was made to implement a *Comisión de Vigilancía*, which has extremely similar duties to those carried out by the Vigilance Body existing in Italy.

During the course of the year the Austrian affiliate was subjected to the General Overview programme. Audits were also carried out at the Bulgarian and Greek affiliates on the most delicate processes.

In Italy an e-learning platform was implemented for the Organisation, management and control model pertaining to law 231/2001, with the aim of promoting its content, dissemination and application. Classroom training sessions were also organised.

Plans for 2015

The Group's commitment to safeguarding the Ethics & Compliance area has been reconfirmed.

There are plans to develop risk assessment processes needed in the countries which have adopted anti-corruption legislation in the meantime.

The *Comisión de Vigilancía* will begin operating at the Spanish affiliate.

At the Czech and Dutch affiliates, audits will be carried out on the most delicate processes.

In Italy the training programme for the Organisation, management and control model pertaining to law 231/2001 will be further extended by means of an e-learning platform and classroom teaching sessions.

Quality, environmental protection and safety

The aim of the Chiesi Group is to carry out timely checks and continually improve its performance in environment and safety.

Management Systems

The application of the Environmental and Safety Management Systems is considered of vital importance in demonstrating to the people at the company, the authorities, clients, suppliers and any interested parties the level of attention it dedicates to health, environmental protection and the careful use of resources.
Now that the certification for both environmental regulation ISO 14001 and safety regulation OHSAS 18001 has been obtained for the Parma sites, the future management is directed at maintaining this certification and introducing management systems at the affiliates.
The maintenance project involves the introduction of approved improvement programmes to comply with the new regulation ISO 14001:2015, which will be revised in the first half of the year.
Following checks made on the basis of an audit, the affiliates will be issued with Group Guidelines, developed in accordance with regulations ISO 14001 and OHSAS 18001.

Environment

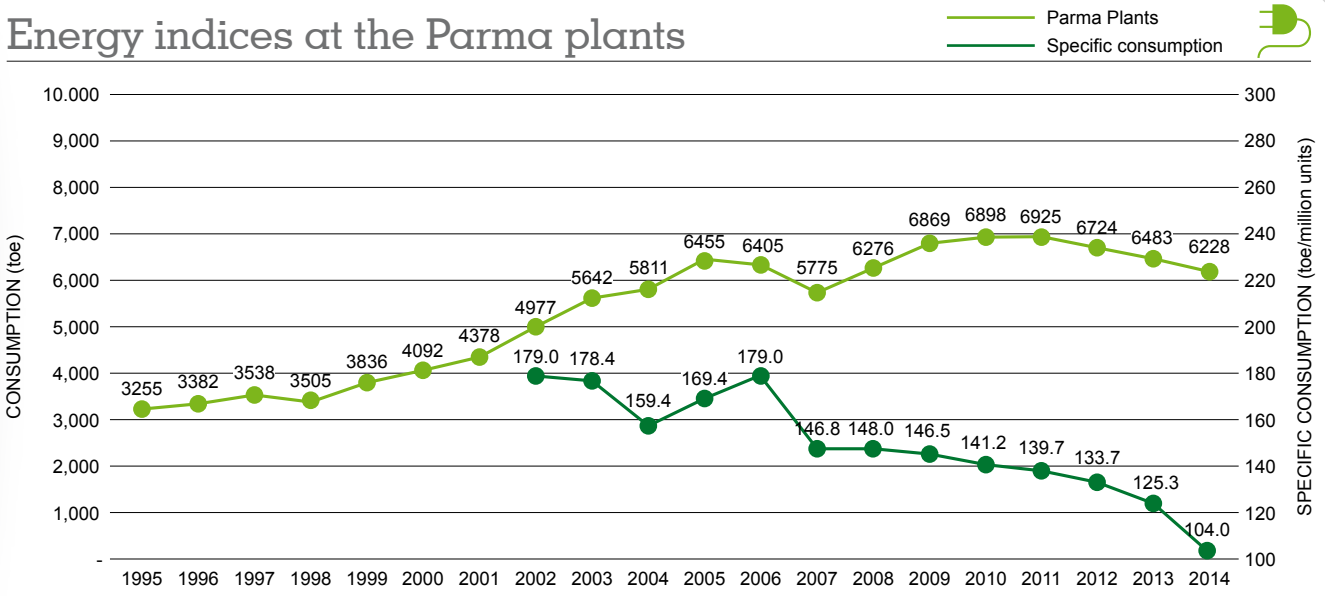
The Group intends to continue with its commitment to the rational use of resources. Particular attention will be paid to implementing low energy consumption production systems and monitoring the Group's energy performance.

Particular focus has been made at the production sites for Curosurf (Parma) and the new NEXThaler plant (Blois) to limit energy consumption, such as the installation of high efficiency heat pumps and boilers, the building of low energy emission constructions and high efficiency air treatment systems. A new solar heating system already began operating in 2014 in Blois to heat sanitary water.
The implementation of a monitoring system is also planned, complying with the requirements set out in the new legislative decree 102/2014, which will ensure the optimisation of the company's systems. This will be integrated with the environmental system.

Certification

ISO 14001
for the environment
OHSAS 18001
for safety

Energy indices at the Parma plants



The table shows how the efforts made to save energy over the years have optimised consumption per unit product.

Indices for the Parma, Blois and São Paulo sites

ASPECT		2013	2014	TREND	NOTES
Energy consumption (methane, electricity, etc.)	TOE(*)/ million units	166	134	↓	**Energy consumption** The improvements made over the years and the solutions adopted have resulted in reduced consumption compared to an increase in the number of units. Specific programmes have been developed in France with the new production plant equipment and in Italy with the new departments and equipment.
Water consumption	m^3/ million units	3,967	2,879	↓	**Water consumption** Levels are decreasing. The water-saving programme for the Research Centre was completed in 2014. New cleaning procedures have been introduced in Brazil.
CO_2 Air Emission (from steam generators)	tonnes/ million units	28,992	26,280	↓	**CO_2 emissions** Levels are decreasing. Outdated boilers have been replaced with one high-efficiency model.
Waste (total amount)	tonnes/ million units	29	26	↓	**Waste** Positive trends. The volume of waste destined for recycling has also increased as a result of specific improvement initiatives.
Hazardous waste	tonnes/ million units	4.5	4.3	↓	
Recycled waste	% of total waste	47	51	↑	
Wastewater	m^3/ million units	2,658	1,850	↓	**Water discharge** This figure is decreasing.
Work related accidents with absence	no.	18	15	↓	**Work-related accidents** The frequency of injuries (number) and severity (lost workdays) are both decreasing. Specific programmes are being planned for the various sites to maintain/improve the levels of safety reached.
Number of lost workdays due to injuries	days	273	266	↓	

(*) Tonne of oil equivalent

Another key aspect is that concerning waste production, and non-toxic waste in particular, as the strict standards required in this sector prohibit re-using waste products or packaging. Particular attention is therefore paid to recycling packaging materials and using reliable suppliers for the transportation and disposal of waste.
The excellent results achieved over the year are mainly due to separated waste collection programmes at the Italian and French sites to recover packaging materials (card and plastic).

The types of production in the Group do not generate significantly high levels of atmospheric emissions. Methane boilers represent the main source. CO_2 emissions were reduced by substituting the two oldest boilers with one high efficiency replacement.

An important contribution also comes from the Brazilian site in Sao Pãulo, where water saving has been made by introducing new cleaning procedures, which involve the use of detergents instead of the large-scale use of water.

Safety

2014 was also a positive year for accidents at work for the Group. The data relating to the frequency and severity of accidents have in fact decreased (see table for indicators).
Furthermore, other initiatives have been introduced - and many others have been planned for 2015 - to improve safety performance through specific training and information programmes aimed at risk prevention.

BBS (Behaviour Based Safety)

This concerns the safety programme based on reinforcing safe conduct. Implemented in the area recording the highest number of accidents, BBS has been gradually extended to the other production plants. The project aims to create a sense of responsibility among workers when making decisions relating to safety in various situations at work.
In 2014 the BBS Project was also implemented in the Solids, Oral and Spray Departments, whereas in 2015 a pilot application will be introduced in the Quality Control and Research laboratories.
The BBS Project has also been introduced in the Company Collective Agreement as a valid prevention and self-monitoring tool.

Training and information

Everyone must take an active part in ensuring their own safety and that of their colleagues! This is why the Group promotes frequent training and information initiatives on safety designed for the entire workforce.
The most recent initiatives include:

- the “5-Minute Safety Programme”, which was implemented in 2014 at the San Paolo site.
- The new safety document: “Safety News” published every three months by the Blois site.

Health

The clinic services provided for employees (including diagnostic tests, flu jabs, I.M. therapy administration and minor medical interventions) have been extended to blood tests and analysis, available on request regardless of which department people work in.
Two more three-year programmes will be launched in 2015, open to everyone working at Chiesi to improve their wellbeing:

- **The chronic obstructive pulmonary disease programme (COPD)** comprises an anti-smoking campaign and the monitoring of lung function indices for the early diagnosis of COPD
- **The cardiovascular disorder prevention programme** comprises the monitoring of blood pressure, and glycaemic, cholesterol and triglyceride levels, as well as tips for a healthy diet.

Other Programmes

In the pharmaceutical industry the use of increasingly active substances at increasingly lower dosage levels represents a significant challenge. This means there is a growing need for device containment to limit as far as possible even accidental exposure on the part of operators.
With this in mind, the 2015 programmes are aimed at monitoring the levels of containment in research and production equipment. These analyses are carried out with state-of-the-art instruments, such as the Standardized Measurement of Particulate Airborne Concentration method (SMEPAC), developed by the International Society for Pharmaceutical Engineering.

Key Programmes in 2015 for Environment and Safety

The following table shows a summary of the objectives set for 2015.

2015 Environment and Safety Programmes

PROGRAMMES	OBJECTIVES
Healthcare prevention activities	COPD and cardiovascular disorder prevention programmes extended to Chiesi workers
Energy diagnosis	Review and improvement of current monitoring system
ISO 14001:2015 implementation	Modification of the existing system to meet new regulatory requirements
Publication of the HSE Corporate Guidelines	Publication of Safety and Environmental Guidelines for the whole Group by the end of the first half of 2015
Extending the BBS method	Extending application of BBS to laboratories
Limiting worker exposure	Applying containment methods to R&D laboratories and the new plants using potent drugs

Other CSR Initiatives

Pharmaceutical Division Italy

Throughout 2014 the Italian affiliate not only continued to operate in accordance with its CSR projects, but also took several actions to safeguard the environment.

One of these actions involved the decision not to include car models with CO2 emissions exceeding 140g/km (A-B-C fuel consumption band) in the company car lists. Furthermore, an innovative idea which won an internal competition has led to the creation of a platform for the management of company forms, ensuring less paper and toner are used and consequently reducing environmental impact.

The EFPIA project was launched, which was needed to align the company with the EFPIA (European Federation of Pharmaceutical Industries and Associations) directive on the transparency of transfers of value between pharmaceutical industries and the healthcare professionals and organisations.
This directive, which came into force on January 1st 2015, requires this data to be published on the company's website by the end of June the following year, and the Italian affiliate therefore worked throughout the year on including a section under CRM dedicated to gathering the data needed to complete the report for the publication of transfers of value in Italy.

Rare Disease Day

The company's commitment to rare diseases also continued in 2014 with its internal communication campaigns created for the Day dedicated to Rare Diseases.

Rare Diseases

0.5% of the population is the threshold required to qualify as a "rare disease" in the EU

0.08% **of the population is the threshold required to qualify as a "rare disease" in the USA**

United Kingdom

Chiesi UK has launched the Chiesi UK Charity Partnership to enable it to give something back to society by supporting community projects. Each year the affiliate partners with a chosen charity to provide financial and volunteer support and contribute to their fundraising.
The Booth Centre was chosen as the Chiesi UK charity partner in 2014, after a thorough selection and approval process. The Booth Centre is one of the UK's leading day centres for homeless people, based in central Manchester. Chiesi UK funded the training room facilities at their new centre, where they provide activities, advice and support for homeless people.

The affiliate has organised appeals for food and other kind of items, and raised funds for the Booth Centre through bake sales, raffles and a sponsored survival run. Through the volunteering programme, teams and individuals have spent time working with the people who use the Booth Centre and their overall feedback was that this has been a touching and rewarding experience.
To raise awareness of the hardships faced by homeless people every single night, six employees joined the "Sleepout", sleeping on the ground outside Manchester Cathedral in freezing temperatures for one night only, helping to raise vital funds for the Booth Centre.
The CEO of the Booth Centre has stated: «*Having Chiesi as an official partner for the Booth Centre means a lot to us: we have the support of the staff at all levels of the organisation. We can't thank the staff at Chiesi enough for their commitment and enthusiasm*».

Germany

In 2014 Chiesi Germany continued to support a variety of non-profit organizations.
As part of the Kick-off meeting, every winner of the internal staff award (Chiesi Excellence Award) had the opportunity to donate a certain amount for an organization of their choice. As a result, the Johannes hospice in Hamburg and Munich was supported. In addition, Chiesi Germany commits to an organization called "Die Tafeln". This association passes edible food meant to go to waste to people in need. Furthermore, an animal welfare organization in Erding and a search and rescue dog service have been supported. Another exciting project is a café offering music therapy for people with dementia, which the affiliate financed the purchase of new instruments for.
A sporting event in which the employees of Chiesi Germany were able to show their physical commitment was the "HSH Nordbank Run", held on Ham-

burg's harbour. By participating in the four-kilometer run in June, the staff supported the campaign "Children Helping Children", which focuses on improving the living conditions of children in Eastern Europe.
Another focus of social commitment in 2014 was the support of the no-profit organization Gye Nyame Kids e.V.. According to the principle "helping others to help themselves", the organization supports street kids and orphans in Ghana by trying to integrate them into new families in their own territory. In addition, the association promotes universal healthcare and the supply of drinking water by constructing wells. Besides the funding provided by the company, the employees also had the opportunity to financially support the project. In light of the initial results achieved, the affiliate intends to support Gye Nyame Kids on a long-term basis.

Greece

During these years of crisis Chiesi Greece has remained a loyal partner to society by continuing its CSR activities.

Support for patients

- In 2014, the Greek affiliate helped patients on a low income, donating medicines to non-profit organizations such as Médecins du Monde Greece, volunteer-run "Social Retail" pharmacies and territorial clinics across the country.
- As in previous years, Chiesi Greece donated Christmas gifts to children hospitalized in the Center for Cystic Fibrosis at the Paediatric Clinic at the Hippocrates Hospital in Thessaloniki.
- The company has continued to support the treatment of children with cystic fibrosis from families unable to afford the costs for therapy.
- It has also continued its support to various public hospital clinics throughout the country by donating medical devices and equipment.

Educational and research support

The affiliate has sponsored various cultural sports, business and training activities, such as:

- the athletics race around the city of Pyrgos, aimed at promoting a healthier life with less lung disease
- the Museum of Cycladic Art and the exhibition "Igea. Health, illness and treatment from Homer to Galen", open until May 31st, 2015, of which the affiliate is the main sponsor
- the "Innovation Project 2.0" competition initiated by the SFEE for innovative ideas in the health sector, giving an opportunity to new scientists and researchers to present their ideas
- 2 scholarships from the Greek Thoracic Society, which were awarded to young researchers at the Pan-Hellenic Congress of Thoracic Diseases.

Chiesi Greece continued to support the Pharmaceutical Department of the University of Athens, providing the PhD study grant for post-graduate students from the Pharmaceutical Department.

The Netherlands

The Dutch “Clean Air for Everybody” foundation set up in 2012 as an initiative run by the Dutch affiliate continues to grow. Its objective is to find a solution to the country’s air pollution problem by providing a platform for all public and private relevant stakeholders, i.e. government, industry, NGOs and the scientific community.

In 2014, the foundation organised a symposium called ‘Air Quality and Pulmonary Diseases: Prevention is better than Cure’ at the Academic Medical Centre (AMC) in Amsterdam. Expert speakers and more than 100 physicians, policy-makers, researchers, entrepreneurs and representatives from NGOs took part in this symposium. The initiative was supported by Elisabeth Bel, Professor of lung diseases at the AMC and also chairwoman of the European Respiratory Society (ERS).

In September 2015 the topic ‘clean air’ will be linked to the ERS in a joint effort between the affiliate and ERS to create public awareness on the importance of clean air for health.

By tackling the issue and finding solutions, the Chiesi initiative stimulates activities for the prevention of health problems, thus protecting people from atmospheric pollution. In this way the company will contribute to creating better living conditions for patients, especially those with respiratory diseases. www.cleanairforeverybody.eu

Spain

Chiesi Spain had an excellent 2014 in terms of the number of CSR actions but most importantly in increasing the level of engagement of its people. To achieve this goal, the affiliate relied on an internal team of people from different areas of the company committed to making Social Responsibility an active part of the company. They succeeded in developing and promoting various activities in the 3 pillars of our CSR strategic overview: the way we do business, manage and develop our people, and relate to our surrounding environment.

On the business side, the affiliateis strongly committed to an ethical, compliant and transparent approach. These principles are put into practice internally with the qualitative evaluation adopted for tenders when selecting suppliers. In this way we can assess their commitment to the community or the level of equity they apply in their own companies. Our supplier FEMAREC, which is in charge of recycling our paper, is a perfect example of this commitment, since they base their initiatives on the social, occupational and cultural integration of people with a high risk of exclusion.

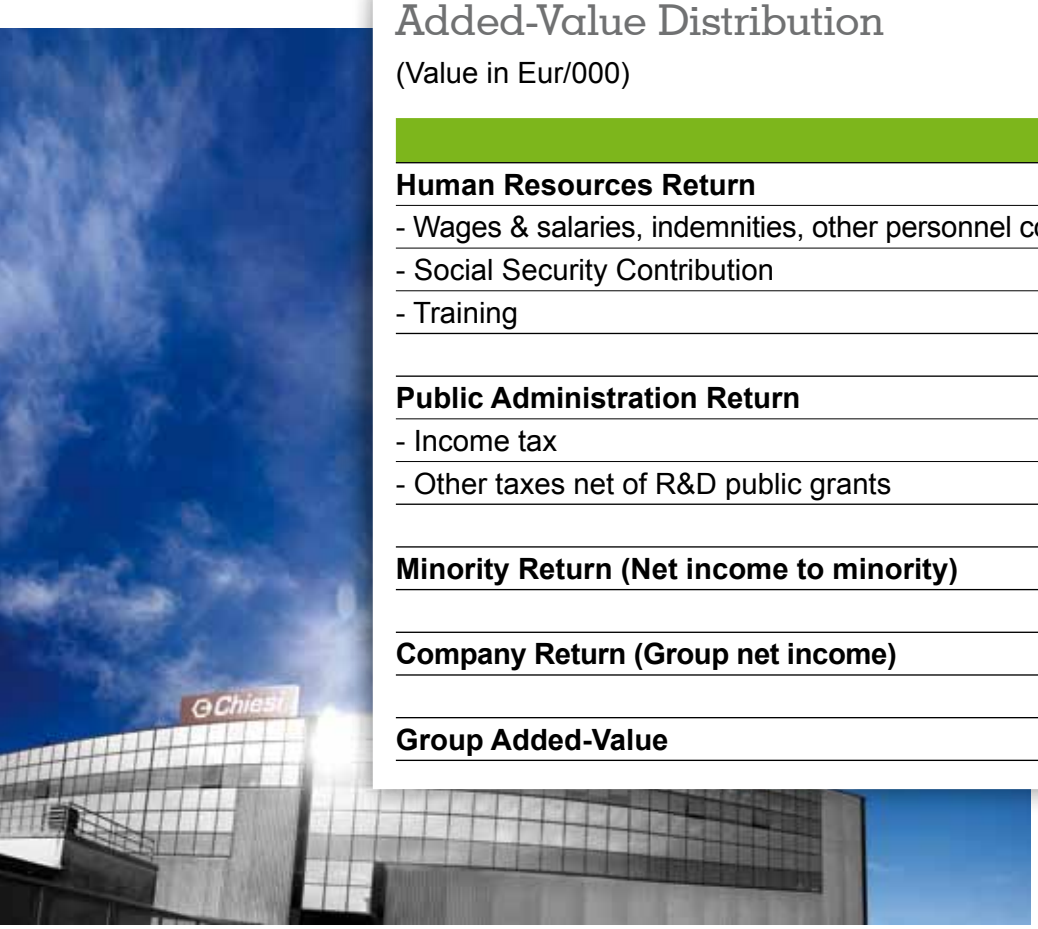
With regard to the people, we are working on initiatives to promote personal and professional development. Chiesi Spain has defined a complete professional training and development path for different roles, including competence development, leadership programmes and training in marketing for a number of people from the affiliate. On a more personal side our Chiesi Vital programme supports various activities to promote a healthy lifestyle among our employees. There are also other initiatives in place, creating opportunities for colleagues

to meet to increase the level of engagement and mutual knowledge of our employees. In 2014 we also took part in the *Rare disease Race*, where more than 40 people from Chiesi Spain and their relatives either helped organise or took part in the run.
The joint initiative continued with “La Viña”, an association which works in a neighborhood close to the affiliate focussing on people with a high risk of social exclusion. We do voluntary work helping them by unloading food from trucks sent by the European Federation of Food Banks (FEBA). This enables the association to support more than 300 low-income families every month. Over the Christmas period we also made a significant contribution by collecting Christmas food and toys for more than 250 children and their families.
Plastic bottle lids were once again collected to buy wheelchairs for children with rare diseases. We also collected around 200 used mobile phones as part of a joint initiative with a foundation that supports research programmes to develop treatments for rare diseases.
The “Chiesi Voluntary Day” 2014 was also held for the first time with L’Olivera, a co-operative of people with severe disabilities. Our contribution was to assist with the grape harvest, so as to reduce its duration from three days to one.

Russia

To promote Corporate Social Responsibility among the people at the affiliate, Chiesi Russia sponsored the “Giuseppe Verdi. Music and culture” exhibition, which was held in Moscow from 1st of July to the 31st of August 2014 to celebrate the 200th anniversary of the birth of the composer.
The affiliate also sponsored a regional no-profit organszation to support cystic fibrosis patients.
Throughout the country, Chiesi Russia employees took part in special Sozidaniye campaigns to raise funds for charity: “Get the children ready for school”, “Currant party” and “New Year wishes 2015”, the last of which involved purchasing toys to donate to children who would otherwise receive no New Year gifts.

Added-Value Distribution



Added-Value Distribution

(Value in Eur/000)

	2014	2013
Human Resources Return	315,495	303,804
- Wages & salaries, indemnities, other personnel costs	251,284	242,201
- Social Security Contribution	52,777	51,266
- Training	11,434	10,337
Public Administration Return	105,801	106,026
- Income tax	95,936	97,240
- Other taxes net of R&D public grants	9,865	8,786
Minority Return (Net income to minority)	0	10,232
Company Return (Group net income)	192,748	183,752
Group Added-Value	614,044	603,814

The added value generated shows an overall growth rate of 1.7%, set against an 8.4% increase in turnover.
In 2014, costs for services increased considerably, which was also due to the progress made with several important clinical trials. As a consequence, the R&D expenditure increased by about 68 million Euro, reaching, 17.6% of the turnover, which is confirmation of the strategic importance and value that the company attributes to this area.
Over 50 % of added value is absorbed by costs and services for the workforce, which grew in proportion to the increase in staff over the course of 2014. Investment has continued in training, a key element for the continuing development of the company.
The increase in the Group's revenues will contribute to the funding of new initiatives and additional investment, which are essential for the future development. During the year, significant investments in the industrial area were made, renewing and improving the Group's high strategic value facilities. Moreover, the acquisition of the totality of shares of Cornerstone Therapeutics Inc. was completed. The American affiliate is now fully own by the company.

The Chiesi Foundation

The Chiesi Foundation is a no-profit organisation founded in 2005 as an expression of Chiesi Farmaceutici's social responsibility.

Mission and values

The mission of the Chiesi Foundation is to capitalise on the Chiesi Group's legacy of knowledge with the aim of promoting the health and alleviating the suffering of patients affected by respiratory diseases and neonatal conditions.
The Foundation affirms and recognises that its own founding values are constituted by:

- the centrality of the human being;
- the observance of universally-accepted ethical principles;
- the responsibility towards the environment and society;
- the dissemination, without boundaries or limits, of science and knowledge;
- the fight against suffering and inequality.

Programmes

The Chiesi Foundation's programmes relate to the following areas of activity:

Chiesi Foundation's programmes

Scientific research and dissemination of knowledge	• Better understanding the patients' needs and improving their management, through the study of physio-pathological mechanisms and phenotypes and in-depth analysis of psychological aspects of patients care • Promoting scientific communication and dissemination of knowledge between public and institutions
Education	• Supporting the scientific activities of young researchers to promote medical-scientific skills, by funding research doctorates • Promoting new training schools for healthcare workers, and public and patient associations as part of joint initiatives with bodies active in the healthcare and education sectors
International cooperation	• Contributing to the development of low- and middle-income countries by providing scientific means and knowledge • Supporting projects which promote the full realisation of the right to health for the populations most in need, with particular focus on neonatal health

Strategy

The Chiesi Foundation carries out its institutional activity by contributing to projects promoted by universities, research centres, foundations and other organisations that have distinguished themselves in the areas in which the Foundation operates. In addition, events and initiatives in the areas of the Chiesi Foundation's institutional interest are sponsored, and granted the use of the logo within the scope of the guidelines provided by the Foundation.

As the Chiesi Foundation's tenth anniversary approaches, it has begun a process of requalifying its mission and instruments. Over the course of 2014, the Foundation defined new strategies both for scientific research activities, which represent the Foundation's main focus, and international cooperation projects, a sector where the Chiesi Foundation has been operating since 2010.

As far as the scientific research programme is concerned, in 2014 the Chiesi Foundation published two Calls for Scientific Research Proposals with deadlines in the June-October period, which defined in detail the type of research projects to be selected, and informed stakeholders about the Foundation's specific areas of scientific interest, pulmunology and neonatology, and the strategic objectives for each of the two fields.

In the pulmunology field in particular, the Chiesi Foundation has set itself the objectives of contributing to the development of new knowledge concerning the relationship between environmental and lifestyle factors and the respiratory tract and to foster scientific communication beyond the medical community. Regarding neonatology, the aim is to improve the knowledge of factors affecting neonatal disease progression and identify strategies to prevent or minimise long-term consequences, thus ensuring a better quality of life for these neonates and their families.

A key strategic change also concerns the approach to international cooperation activities. The Chiesi Foundation has chosen to concentrate its resources in one specific area, i.e. neonatology, and has decided not to limit itself to the provision of funding for projects run by third parties, but to take on a more active role, designing and developing its own projects and actively looking for new national and international partners.

2014 activities

Scientific research and dissemination of knowledge

One of the main institutional aims of the Chiesi Foundation is the promotion of high level medical-scientific research activities with a particular focus on the study of respiratory or neonatal diseases.

During 2014, the Foundation provided continuous support for four research projects that were already underway in 2013:

- *New therapeutic strategies for the reduction of neonatal mortality in the Middle East: sustained lung inflation and brain cooling*, Dr. Gazzolo – Hospital SS. Antonio e Biagio and Cesare Arrigo;
- *New strategies in neonatal resuscitation: biochemical and respiratory effects*, Prof. Lista – Hospital "V. Buzzi";
- *Elaboration of a flow chart to assess the role of the small airways in the phenotypic expression of bronchial asthma*, Dr. Contoli – University of Ferrara;
- *Long-term clinical, functional and pharmacoeconomic phenotypisation of patients with Small Airways Disease (SAD) in Asthma*, Prof. Dal Negro – R&CG Srl.

In addition, five new research projects have been selected and are now underway:

- *Rate of growth in the first year of life and wheezing at 3 years of age: nature or nurture*, Dr. Brescianini – Istituto Superiore di Sanità;
- *Genetic diagnosis of pulmonary diseases in newborns and infants: a genomic approach through Next Generation Sequencing*, Dr. Cutrera and Dr. Danhaive – Hospital Bambin Gesú;
- *Echographic assessment of the postnatal pulmonary adaptation in term newborns*, Dr. Gizzi – Hospital S. Giovanni Calibita Fatebenefratelli;
- *Clinical, functional and inflammatory characterisation of an asthmatic patient cohort: identification of phenotypes for a personalised pharmacological approach*, Dr. Contoli – University of Ferrara;
- *The mechanism of mirror neurons in social cognition: an electroencephalographic high- density study*, Prof. Gallese – University of Parma.

One of the studies assigned an unrestricted grant by the Chiesi Foundation was published in 2014 in a peer-reviewed journal:

- Extent and prevalence of cognitive dysfunction in chronic obstructive pulmonary disease, chronic non-obstructive bronchitis, and in asymptomatic smokers, compared to normal reference values. Dal Negro *et al.*, *International Journal of COPD*.

The Chiesi Foundation is committed to promoting not only the generation of new scientific knowledge, but also its dissemination amongst the scientific community, the public and institutions.

Throughout 2014 the following initiatives were supported:

Respiration day

The tenth edition of Respiration Day was held at the Paganini Auditorium in Parma on the 30th of May 2014. This international high-profile scientific event gives clinicians and researchers the opportunity to compare and exchange ideas and experiences regarding the latest developments in pulmunology. The aim of the congress is to contribute to raising the level of awareness about respiratory diseases and improve their prevention.

Respiration Day 2014 was dedicated to the theme: "*Managing the patient with respiratory diseases: a wider perspective*" and set itself the aim of closely analysing not only the physiopathological aspects that characterise respiratory diseases, but also the possibility of treating them, whilst highlighting the related social impact.

Breathing Himalaya – Learning to Breathe

For the second year running, the Chiesi Foundation supported the project *Breathing Himalaya – Learning to Breathe*, as a joint initiative with the Ev-K2-CNR Association, a no-profit organisation with twenty years' experience in developing scientific and technological research projects at high altitudes, which stands out because of the specificity and excellence of its results achieved in the field of international scientific investigation.

The initiative addresses the issue of the prevention and treatment of chronic obstructive pulmonary disease (COPD) through a project studying the incidence of COPD in the Himalayan populations of Nepal, exposed almost exclusively to sources of indoor pollution.

An interactive, touring photographic exhibition is the main tool used to inform and raise awareness in schools, associations and families about COPD risk factors and diagnostic techniques and find out more about the Himalayan environment and its peoples.

European Respiratory News

In 2014, the Chiesi Foundation supported the publication European Respiratory News, a scientific journal examining issues in the pulmunology field, a reference publication for specialists.

Education and support for young researchers

The Chiesi Foundation supports the scientific activities of young researchers with the aim of promoting academic research and contributing to the development of new medical-scientific competences. Over the course of 2014, the Foundation began funding three **research doctorate projects**, each of a three-year duration:

- *Restoring mutant CFTR with Nanobodies,* Dr. Cedric Govaerts, Université Libre de Bruxelles;
- *Design, synthesis and biological assessment of new broad spectrum antivirals for the treatment of enterovirus and rhinovirus infections*, Dr. Marco Radi, University of Parma;
- *Microparticles and PPAR-gamma receptors: potential new therapeutic targets in bronchial asthma and COPD*, Dr. Sandra Brunelleschi - University of Eastern Piedmont.

The Chiesi Foundation also continues to support the **Maurizio Vignola Award for Innovation in Pneumology**, a joint initiative set up with the European Respiratory Society (ERS) to promote scientific research and develop knowledge in the field of respiratory diseases. The 2014 award was assigned to two young researchers:

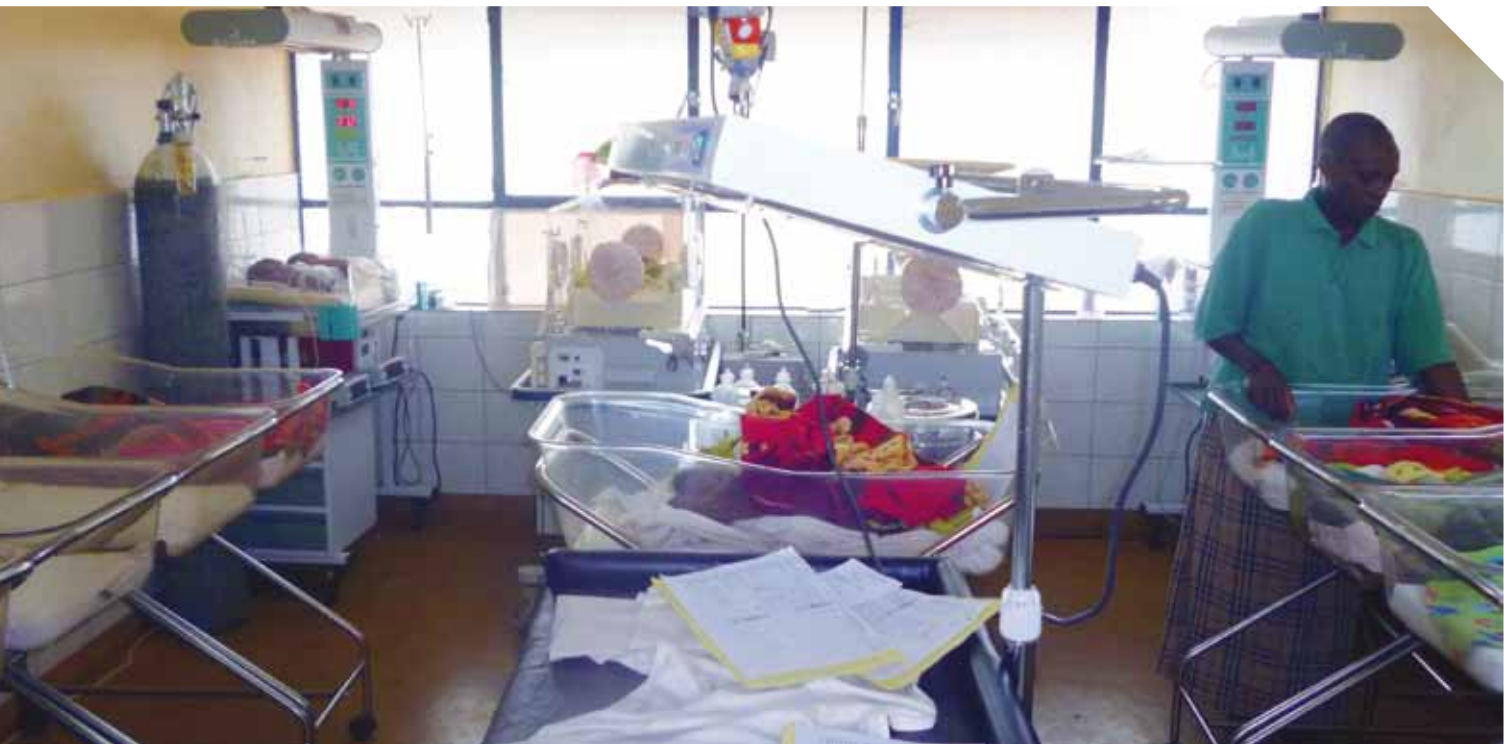
- Klaus Bonnelykke for his work published in 2013 in *Nature Genetics*: "A genome-wide association study identifies CDHR3 as a susceptibility locus for early childhood asthma with severe exacerbations";
- Kristin Westphalen for her work published in 2013 in *Nature*: "Sessile alveolar macrophages communicate with alveolar epithelium to modulate immunity".

In addition to providing support for the scientific activities of young researchers, the Chiesi Foundation jointly promotes educational initiatives and innovative training schools with associations and other organisations both at national and international level, which are active in the fields of social and medical care, education and the support of the disadvantaged and medical-scientific culture, providing them with the necessary technical-scientific support and materials.
In 2014, the Chiesi Foundation began supporting two educational initiatives whose particular focus is the respiratory disease area.

- **RESPIRO Project**, an initiative run by the Serena Foundation, which makes training courses available to parents of children affected by neuromuscular diseases with a high risk of respiratory complications at the NEMO Clinical Centre. The aim is to monitor and check respiratory procedures and management, in order to improve the quality of life of the children and their families.
- **Partners in care – "Optimizing Asthma & COPD Diagnosis and Chronic Disease Management in Guyana"**, a medical training project coordinated by Prof. Robert Levy from the British Columbia University jointly with the British Columbia Lung Association. This three-year initiative focusses on the development of specific clinical skills for the management of chronic respiratory diseases, such as asthma and chronic obstructive pulmonary disease (COPD). The first phase centres on the management of asthma by introducing the spirometer as a diagnostic instrument. The courses, initially designed for staff at the Georgetown Public Hospital Corporation (GPHC) located in Georgetown, the capital, will then be run at other national healthcare structures.

International cooperation

The Chiesi Foundation is committed to supporting international cooperation projects in the healthcare sector, with a strong focus on the long-term sustainability of initiatives and their gradual economic independence. From the very beginning, the Foundation prioritised the setting-up of initiatives whose objective was improving the conditions of neonates.
Over the course of 2014, the Chiesi Foundation decided to focus future international cooperation activities exclusively within the scope of **neonatology** through a new and ambitious intervention programme: the **NEST Project – Neonatal Essential Survival Technology**. This programme is designed and developed for a five-year period, with the aim of contributing to a reduction in neonatal mortality rates in low- and middle-income countries.
The NEST Project aims to tackle the issue of improving the quality of neonatal care in low resources countries, both by promoting **training programmes on basic neonatal treatment for local healthcare staff**, and providing **basic drugs and medical equipment for neonatal care units** characterised by levels of technology, access and maintenance costs in line with limited resources hospitals. The NEST Project adopts a specific approach for every hospital structure it deals with, since the target group of countries includes territories with different healthcare structures and varying levels of financial and human resources.
The NEST Project marks a significant change in the Chiesi Foundation's strategy as it involves the Foundation taking an active part in designing and developing activities, abandoning the function of a body merely grant-making. The Chiesi Foundation has chosen neonatology as a strategic focus to exploit the potential of the network and experience it has gained over the years, with the aim of becoming a catalyst of ideas, skills and resources in the sector.
Within the scope of the NEST Project, the first pilot interventions have been introduced in contexts and hospitals where the Chiesi Foundation operates and can collaborate directly with local healthcare workers.



Burkina Faso

Since 2010 the Chiesi Foundation has worked jointly with the Saint Camille Medical Centre in Ouagadougou, managed by the Camillian Fathers. The Foundation supports the neonatology ward at the Centre, developing projects aimed at transferring scientific means and knowledge to bring the treatment standards for premature and sick neonates in line with the latest healthcare protocols. In 2014, a project was begun to expand the existing neonatology ward and provide the necessary additional medical equipment and training to improve the quality of neonatal care.

Benin

The Chiesi Foundation collaborates with the Fatebenefratelli Congregation, which runs the Saint Jean de Dieu Hospital in Tanguietá, where a new neonatal ward was inaugurated in 2012 partly with the Foundation funding. Starting from 2014, the Chiesi Foundation now provides a three-year study grant for a young doctor specialising in paediatric surgery, in order to ensure healthcare worker retention and guarantee the regular functioning of the ward. Furthermore, funding was provided in 2014 to complete the construction work on the Hospital's welcome centre, designed for patients coming from remote areas and requiring day care or rehabilitation after hospitalisation.

Burundi

Over the course of 2014, the Chiesi Foundation began a three-year joint initiative with Cardinal Tonini's Pro-Africa Foundation, relating to a training/healthcare project for the neonatal ward which was built within the new maternal and infant Centre at the Ngozi Hospital. The Chiesi Foundation is also involved in reorganising the neonatal care and opening the ward by equipping it with adequate medical apparatus and training local staff.

Azerbaijan

In 2014, the Chiesi Foundation began supporting the project "National School for Neonatology in Azerbaijan". The training programme consists of courses involving international experts in intensive care for neonates and is designed for the most motivated and specialised local professional doctors. The objective of the training is to share skills and international experiences in neonatal care to reduce the mortality rate of premature neonates in the country.

Lastly, over the course of 2014, the Chiesi Foundation lent its support to three organisations:

- The *Salute e Sviluppo* NGO, which works with the Camillian Fathers operating in the Central African Republic. The project "Emergency in Central Africa" was funded in 2014 with the aim of improving nutrition in the infant population of Bossemptelé, a small town in the Central African Republic, by providing medical care and nutritional support by distributing food parcels.
- The *Burmese Migrant Workers' Education Committee (BMWEC)* is an organisation which runs the schools and educational centres in Mae Sot, a small town on the border between Thailand and Burma. These centres provide the immigrants' sons with a basic level of education, healthcare and protection.

  In 2014, the funding for the project was raised thanks to the charity event "*Boundary Children*", organised by the Chiesi Foundation during the month of June. Funds for a total of 67,417 Euro raised at the event met the running costs of some schools not only for the 2014-2015 academic year, but also the following year.
- The *Apurimac Association*, which promotes a project for social and healthcare improvement to guarantee the right to health for women and children living in the Apurimac regions, an area of Peru in the heart of the Andes. The project consisted of a training programme for healthcare workers at the Maiani Polyclinic – the Saint Rita of Cuzco Centre and support for health campaigns in villages in the Andes.

Balance sheet

Compared to 2013, the Chiesi Foundation received more donations both from the Founders and other donors. This increase in available resources has enabled the Foundation to confirm and consolidate its commitment to supporting scientific research projects, dissemination of knowledge, training and international cooperation.

2014 Balance sheet (Value in Eur)

	Amount released 2014
Scientific research	235,300
Dissemination of knowledge	79,881
Education	110,375
International cooperation	143,001
Communication activities	5,200
Staff expenditures	24,334
Administrative costs	36,689
TOTAL OUTGOINGS	**634,780**

	2014 funds
Chiesi Farmaceutici	501,000
Valline	80,000
Other donations	94,812
TOTAL DONATIONS	**675,812**
From financial management	378
TOTAL INCOME	**676,190**

Glossary

Advanced Therapies: biologics, based on genetic material, cells and tissues that have been proven effective in the treatment of various diseases. The advanced therapy medicinal products include all new generation therapeutic interventions defined as: gene therapy, cell therapy and tissue therapy.

Alpha-mannosidosis: lysosomal storage inherited syndrome, characterised by immune deficiency, facial and skeletal abnormalities, hearing and cognitive impairment. It occurs in about 1 in every 500,000 babies.

Beclomethasone dipropionate (BDP): synthetic glucocorticoid with potent anti-inflammatory action. When taken through inhalation, this drug reaches the lungs directly where it exerts its effect. Its low level of absorption in the rest of the body ensures negligible systemic side effects.

Chronic Obstructive Pulmonary Disease (COPD): term used to indicate two related lung diseases – chronic bronchitis and emphysema. Both diseases are characterised by chronic and progressive obstruction of the airways, making it difficult to breathe.

Customer Relationship Management: the process of managing customer relationships, which is accomplished through four principal activities: the acquisition of new customers, the development of relationships with key customers, the fidelization of key customers, the transformation of existing customers into ambassadors of the qualitiy characterizing the products and/or services of the company. Although the processes of CRM are often supported by IT systems, these latter have a purely instrumental function and by no means can replace the relational system of the company .

Cystic Fibrosis (CF): chronic hereditary disease of the lungs and the digestive system, which currently affects roughly 70,000 people worldwide. A mutated gene creates a protein that causes production of a thick viscous mucus that accumulates and renders breathing difficult. This in turn makes it easier for secretions to build up and consequently promotes the development of dangerous infections. In the digestive system the mucus tends to block ducts in the pancreas and prevents digestive enzymes from working in the intestines, which leads to malabsorption of food and stunted growth.

Dry Powder Inhaler (DPI): a device for administering drugs in the treatment or control of respiratory diseases and conditions.

Generally Accepted Accounting Principles (GAAP): term used to refer to the standard framework of guidelines for financial accounting used in any given jurisdiction; generally known as Accounting Standards. GAAP includes the standards, conventions, and rules accountants follow in recording and summarizing transactions, and in the preparation of financial statements.

Hydrofluoroalkanes (HFA): propellants used in some inhalers for the management of asthma. They do not damage the ozone layer. A propellant is a gas which facilitates the diffusion of an inhalant drug in the lungs.

Lipoprotein lipase deficiency: very rare inherited disease due to which patients cannot metabolize the fats in the blood, which causes inflammation of the pan-

creas (pancreatitis), a condition extremely serious, painful and potentially deadly.

Long-acting Beta-agonists (LABA): drugs which open peripheral and central airways and keep them unobstructed by relaxing bronchial smooth muscle. LABAs are often administered with steroids in inhalation form as a long-term bronchodilation treatment for patients with moderate to severe asthma or other chronic lung diseases.

Manufacturing Execution Systems (MES): solutions that support the primary production processes in a production plant. These applications close the gap between ERP systems and production equipment control or SCADA (Supervisory Control And Data Acquisition) applications. MES applications have become essential to support both real-time production control as well as the data collection and reporting ("manufacturing intelligence") necessary to improve production performance.

Muscarinic agonists: defined as direct parasympathomimetics. Among the main pharmacological effects, they have the potential to cause contraction of the smooth muscle of the bronchi.

Muscarinic antagonists: defined as parasympatholytic. Among the main pharmacological effects, they have the potential to cause relaxation of bronchial smooth muscle.

Piroxicam β-cyclodextrin (PBC): a successful example of "host-guest" technology, whereby the host, a starch derivative known as β-cyclodextrin, solubilises the guest, an anti-inflammatory drug known as piroxicam, thus enhancing the pharmacological properties of its active ingredient.

Pressurised Metered-Dose Inhalers (pMDI): a device which ensures that a specific quantity of drug is delivered to the lungs. Widely used by the Chiesi Group for its products, it is commonly employed in the treatment of asthma, Chronic Obstructive Pulmonary Disease (COPD), and other respiratory conditions.

Pulmonary dysplasia: lung disease that usually starts as a RDS and then tends to become chronic and determine the need to assist the infant in terms of breathing

Respiratory Distress Syndrome (RDS): disease typically affecting premature neonates caused by insufficient production of endogenous surfactant and immature lungs. The condition may also be due to a genetic problem linked to the production of proteins associated with the surfactant. RDS affects 1% of neonates and is the main cause of mortality in premature infants.

Unit-Dose Vials (UDV): non-reusable sterile containers holding a single dose of drug. Pharmaceutical products packaged in vial or mono-dose bottles are easily recognisable and simple to use.

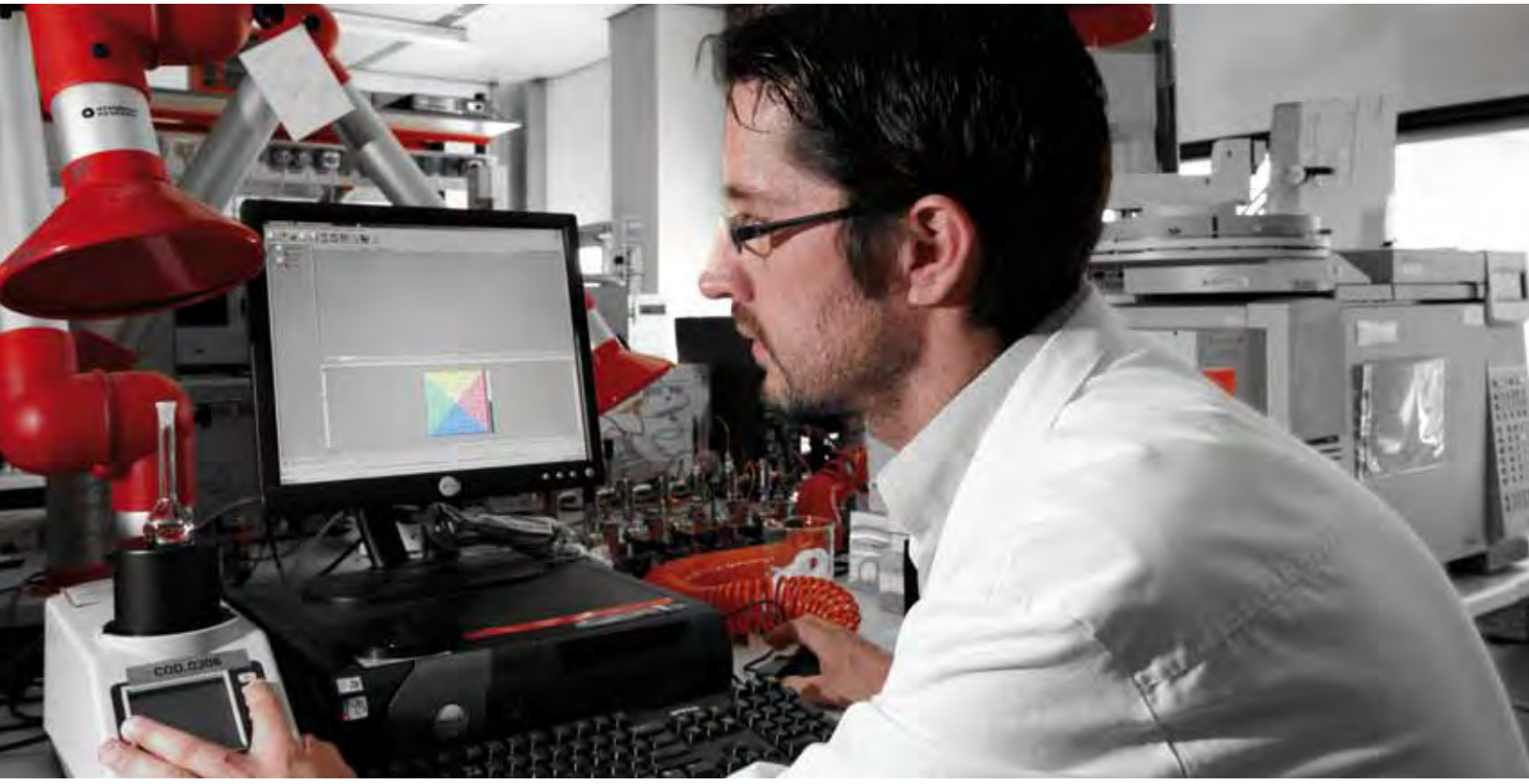
Ulcerative Colitis (UC): inflammatory bowel disease (IBD) which causes lesions known as ulcers to develop in the lining of the colon and rectum. Ulcers form where the inflammatory process destroys the cells which normally line the colon, causing in bleeding and pus. The inflammation may also result in frequent bowel movements, and therefore diarrhoea.

Spacer: a type of add-on device used by asthmatics to increase the efficacy of the inhaler.

Chiesi Farmaceutici S.p.A.

Proprietary Brands

Atem
Atimos
Becloneb
Beclospin
Bethkis
Bramitob
Brexidol
Brexin
Clenil
Clenny
Clipper
Clody
Combair
Curosurf
Cycladol
Flamexin
Fluibron
Fostair
Foster
Fostex
Holoclar
Hyaneb
Innovair
Inuvair
Iperten
Manyper
Modulite
Nexthaler
Peyona
Rinoclenil
Vivace



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